No. 88-704

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1988

IN RE: BENDECTIN LITIGATION
SARAH ANN HOFFMAN, et al.
ELIZABETH ANN DAVIS, et al.
and SHANE ROSS WOOD, ETC. et al.
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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QUESTIONS PRESENTED

1. Where a trial court orders trifurcation of issues for trial, resulting in separate proceedings for causation, liability and damages are plaintiffs denied a fair and impartial trial?

2. Where plaintiffs are arbitrarily excluded from the trial of their case, without the benefit of a hearing, are plaintiffs denied their rights of due process as guaranteed by the Fifth and Seventh Amendments to the United States Constitution?

3. Where a plaintiff alleges violation of a federal statute, which provides no private right of action, in his complaint filed in federal court, does that allegation, alone, impart federal question jurisdiction?

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SARAH ANN HOFFMAN, et al.
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Petitioners,

v.

MERRELL DOW PHARMACEUTICALS INC.,

Respondent.

Petition For a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

Petitioners, plaintiffs below, pray that a writ of certiorari issue to review the decision and order of the United States Court of Appeals for the Sixth Circuit affirming the decision of the United States District Court for the Southern District of Ohio denying plaintiffs' Motions for Judgment *Non Obstante Verdicto* and for a New Trial and holding that the District Court did have federal question jurisdiction in suits brought by Ohio citizens in federal courts.

OPINIONS BELOW

The opinion of the court of appeals is reported at F.2d ___ (6th Cir. 1988) and is printed in the Appendix at 2a. The opinion of the district court is reported at 624 F.Supp. 1212 (S.D. Ohio, 1985).

JURISDICTION

The decision of the United States Court of Appeals for the Sixth Circuit was entered and filed on August 30, 1988. The 60th day after such decision was Saturday, October 29, 1988. This petition was filed on or before Monday, October 31, 1988. The jurisdiction of this Court is invoked under 28 U.S.C. Sec. 1254(1) and 2101(b).

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

This case involves allegations of violations of certain sections of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, as amended, 21 U.S.C. Sec. 301 *et seq.* (1982 ed., Supp. II) the pertinent provisions of which are set forth in the Appendix at 83a. Also involved is the due process clause, U.S. CONST. amend. V, and the right to a jury trial, U.S. CONST. amend. VII.

STATEMENT OF THE CASE

This petition follows plaintiffs' appeal to the United States Court of Appeals for the Sixth Circuit from a judgment in favor of defendant, Merrell Dow Pharmaceuticals, Inc., entered after a jury verdict in a consolidated trial of in excess of eight hundred cases

in the United States District Court for the Southern District of Ohio.[1]

Petitioners are parents and children who brought suit against the respondent, Merrell Dow Pharmaceuticals, Inc., alleging that birth defects suffered by the children were caused by their mothers' ingestion during pregnancy of defendant's anti-nausea drug Bendectin. Plaintiffs' complaints requested relief upon the grounds of negligence, breach of warranty, strict liability, fraud, failure to warn and gross negligence, as well as violations of the misbranding provisions of the Federal Food Drug and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. Sec. 301 *et seq.* (1982 ed. Supp. II).

Prior to trial, the trial court issued two extraordinary rulings which constituted in large part the basis of plaintiffs' late appeal to the court of appeals. The first ruling was an order of trifurcation. The second ruling was an order, issued without a hearing meeting the requirements of due process, banning all child plaintiffs under the age of ten and all child plaintiffs evidencing visible birth defects and deformities from the courtroom during trial.

The trifurcated trial commenced on February 1, 1985, upon the sole issue of "causation". If plaintiffs were successful, a second trial would be held upon the issue of liability. A third trial could then follow as to damages. On March 12, 1985, after twenty-two trial days, a jury verdict was rendered in favor of

[1] The approximately 800 individual Petitioners in this action are listed in the Notice of Appeal found herein in the Appendix at 85A.

defendant when the jury answered the following interrogatory in the negative:

> Have the plaintiffs established by a preponderance of the evidence that ingestion of Bendectin at therapeutic doses during the period of fetal organogenesis is a proximate cause of human birth defects.

(App. at 38a).

Following the entry of judgment for defendant, a timely appeal was taken by plaintiffs to the United States Court of Appeals for the Sixth Circuit, wherein plaintiffs argued that the trial court abused its discretion by trifurcating for trial the issues of causation, liability and damages, thereby causing plaintiffs to be unduly prejudged and creating a sterile or laboratory type trial environment, and exclusion of plaintiffs from the courtroom during trial deprived plaintiffs of their constitutionally protected rights to due process.

During the pendency of the appeal, this instant Court granted and heard the Petition for Certiorari of defendant, Merrell Dow Pharmaceutical Inc., centering upon a jurisdictional question stemming from allegations in plaintiffs' complaints that the drug Bendectin was misbranded in violation of the Federal Food, Drug and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. Sec. 301 *et seq.* (1982 ed., Supp. II). *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986). The plaintiffs at issue were residents of Canada and Scotland and had filed their complaints in the Court of Common Pleas in Hamilton County, Ohio. Thereafter, defendant had removed these cases to the United States District Court for the Southern District of Ohio, arguing the actions

were founded in part upon an alleged claim arising under the laws of the United States. The cases were consolidated with all other Bendectin cases before the district court. Plaintiffs requested a remand to the state forum upon the basis that the federal court lacked jurisdiction.

In its opinion decided July 7, 1986 this Court held:

> We conclude that a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim "arising under the Constitution, laws or treaties of the United States." 28 U.S.C. Sec. 301.

Merrell Dow Pharmaceuticals Inc. v. Thompson, *supra*, at page 817.

On August 14, 1986, shortly after the decision of this instant Court was rendered, the plaintiffs filed a motion before the court of appeals requesting the remand to state court, or dismissal without prejudice for further proceedings in the state court, of approximately two hundred cases which had been originally filed by plaintiffs who were residents of the State of Ohio and had been consolidated with those other cases tried before the district court and were currently before the court of appeals. Previously, on August 27, 1985, the district court had ordered the cases of all Ohio plaintiffs dismissed and had remanded all cases removed from the Ohio state courts, however, this order was stayed and had not been effectuated. The basis of plaintiffs' motion before the court of appeals

was lack of federal jurisdiction pursuant to *Merrell Dow Pharmaceuticals Inc. v. Thompson, supra.*

On August 30, 1988, the United States Court of Appeals for the Sixth Circuit decided and filed its opinion. Therein, the court affirmed the trial court's decision to trifurcate and affirmed the trial court's decision to exclude plaintiffs from the courtroom. Further, the court dismissed without prejudice thirteen actions brought by Ohio citizens in federal court in which the defendant had concealed that the district court was without jurisdiction to render judgment. The court held it would not disturb that part of the district court's post-trial order remanding all cases brought by Ohio citizens in state courts back to the courts from which they were removed. However, as to all other suits brought by Ohio citizens in federal courts, which suits were similar to those which were the subject matter of *Merrell Dow Pharmaceuticals Inc. v. Thompson, supra,* the court of appeals held that the district court did have jurisdiction and that the adverse jury verdict was binding upon those plaintiffs.

REASONS FOR GRANTING THE WRIT

This case presents three questions of import which should be addressed by this Court.

The first addresses the issue of the scope and breadth of Rule 42(b) of the Federal Rules of Civil Procedure and whether that rule may be interpreted so as to permit trifurcation of issues for trial. Inherent in this question is the issue of the degree of prejudice which must be demonstrated to establish an abuse of discretion by the trial court. Trifurcation of issues for trial is a procedure which departs from the

usual and accepted course of judicial proceedings and is an important question of federal procedure which has not been settled by this Court.

The second question presented is that of the right of a plaintiff to be present at the trial of his or her own case. The court of appeals' decision affirming the trial court's arbitrary exclusion of plaintiffs from the courtroom without a hearing meeting the requirements of due process conflicts with its recent holding in *Helminski v. Ayerst Laboratories*, 766 F.2d 208 (6th Cir. 1985), *cert. denied*, 474 U.S. 981 (1985), conflicts with past decisions of this Court, and sanctions a departure by a lower court from established due process procedures, thereby requiring intervention and clarification by this Court.

The final question presented is that of the federal question jurisdiction of a district court over suits in which a private cause of action is implied pursuant to the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, as amended, 21 U.S.C. Sec. 301, *et seq.* (1982 ed. Supp. II). The court of appeals' decision finding such federal question jurisdiction conflicts not only with its prior decision in this case as reported in 766 F.2d 1005 (1985) but also with the import of the instant court's decision in *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986).

I. WHERE A TRIAL COURT ORDERS TRIFURCATION OF ISSUES FOR TRIAL, RESULTING IN SEPARATE PROCEEDINGS FOR CAUSATION, LIABILITY AND DAMAGES THE PLAINTIFFS ARE DENIED A FAIR AND IMPARTIAL TRIAL.

A. TRIFURCATION IS INHERENTLY PREJUDICIAL TO THE PLAINTIFFS, CREATES A STERILE OR LABORATORY ENVIRONMENT FOR TRIAL AND DENIES THE PLAINTIFFS A FAIR AND IMPARTIAL TRIAL.

In the instant case, the trial court ordered trifurcation of the issues of causation, liability and damages for trial, relying upon Rule 42(b) of the Federal Rules of Civil Procedure.

Federal Rule of Civil Procedure 42(b) permits a separate trial of any claim or separate issue in furtherance of convenience, to avoid prejudice, or when a separate trial may be conducive to expedition and economy. However, the right of trial by jury as declared by the Seventh Amendment to the Constitution must be preserved in the application of Rule 42(b) F.R.C.P.

In determining whether a separate trial of an issue should be ordered, the court must balance the potential convenience and economy offered by a separate trial with the concept of the complexity of legal theories and factual proof presented by the case as a whole, the risk of jury confusion, the risk of prejudice to a party, whether the disposition of a separate issue in the first trial will dispose of or simplify the issues to be raised in the second trial, and whether a fair and impartial trial is provided all litigants. *In re Beverly Hills Fire Litigation*, 695 F.2d 207 (6th Cir. 1982), *cert. denied sub nom. Bryant Electric Co. v. Kiser*, 461 U.S. 929 (1983) (hereinafter *Beverly Hills*);

Moss v. Associated Transport, Inc., 344 F.2d 23 (6th Cir. 1965). This Court has made clear that the separation of issues for trial should be limited to issues that are so distinct and separable that separate trials can be conducted without prejudice. *Gasoline Products Co. v. Champlin Refining Co.*, 283 U.S. 494 (1931).

It is plaintiffs argument that trifurcation of a case for trial is inherently prejudicial to the parties and in all instances denies the litigants a fair and impartial trial.

The Court of Appeals for the Sixth Circuit recognized for the first time the possibility of the trifurcation of a trial in *Beverly Hills, supra.* Therein, the same trial court as in the instant Bendectin case ordered trifurcation, and severed the issue of causation for trial from the issues of liability and damages. After trial on causation, the jury returned a special verdict in favor of defendants, finding that aluminum wiring had not caused the fire which was the subject matter of plaintiffs' procedure, but with the following admonitions:

> A strong argument can, it is true, be made against the bifurcation of a trial limited to the issue of causation. There is a danger that bifurcation may deprive plaintiffs of their legitimate right to place before the jury the circumstances and atmosphere of the entire cause of action which they have brought into court, replacing it with a sterile or laboratory atmosphere in which causation is parted from the reality of injury . . . Here, however, it is only fire itself, a major disaster in Kentucky history by all standards, was generally known

> to the jurors from the offset. Further, the proofs themselves, although limited, were nonetheless fully adequate to apprise the jury of the general circumstances of the tragedy and the environment in which the fire arose . . .

Id at page 217.

The court of appeals reversed upon other grounds and ordered a new trial, but in so going, strongly suggested that upon retrial, a separate trial on the issue of causation not take place. Upon retrial, all liability issues were tried together, resulting in a plaintiffs' verdict.

The set of circumstances present in *Beverly Hills, supra.*, which the court of appeals found offset the inequities inherent in trifurcation, were not present in the instant Bendectin case. Moreover, it would be highly improbable that such a special set of circumstances would arise again.

As a result of trifurcation, the Bendectin trial did take place in a sterile, laboratory type atmosphere, resembling more a scientific inquiry than an actual trial of a case or controversy.

Trial procedures were distorted to such a degree that the rights of the litigants to a fair and impartial trial were sacrificed in favor of a preoccupation with speed of disposition. Only expert testimony was permitted at trial. No fact witnesses or plaintiffs were permitted to testify. No plaintiffs evidencing birth defects or deformities were permitted in the courtroom. No photographs or representations of the birth defects at issue were permitted to be shown the jury. Evidence of defendant's past course of conduct in

producing, testing and distributing its other teratogenic drug, Thalidomide, was not permitted. The trial court was so concerned with defendant's connection to Thalidomide that no reference whatsoever to the drug was permitted during trial. Even plaintiffs' experts' qualifications were censored so that their background, experience and work relating to Thalidomide was not made known to the jury. Evidence of defendant's past course of conduct of fraud, misrepresentation and mislabeling drugs was not permitted.

A trifurcation order, as in the instant case, presented fundamental problems of fairness because the typical procedure in litigation does not involve the splitting up of a case element by element, and trying each point to the jury separately. Instead, a plaintiff's entire case is presented to the jury at once, thereby preventing the isolation of issues in a sterile atmosphere.

Further, in the instant case, over 800 plaintiffs, whose mothers took the drug Bendectin at different times and places and under different circumstances, were involved. By not allowing the plaintiffs to present evidence as to how each was individually affected by the drug and the circumstances pursuant to which the drug was taken, plaintiffs were prejudiced in their attempt to establish the required elements of their case.

Simply because a litigant shares his complaint with 800 other claimants is not a reason to deprive him of the day in court he would have enjoyed had he been the sole plaintiff. When a litigant does not get a proper day in court, the litigant is deprived of the constitutionally guaranteed right to a jury trial, and

is denied due process because of the imposition of a procedural device.

Plaintiffs ask this Court to prevent such a case-management tool from becoming a penalty to injured plaintiffs seeking relief through the legal system.

B. ABUSE OF DISCRETION MAY BE ESTABLISHED BY A SHOWING THAT "ANY" PREJUDICE OCCURRED, AND NOT ONLY BY A SHOWING THAT "UNDUE" PREJUDICE OCCURRED.

In its opinion in the instance case, the Court of Appeals for the Sixth Circuit held that to support a finding of abuse of discretion in the ordering of a separate trial pursuant to Rule 42(b) of the Federal Rules of Civil Procedure, a party must show "undue" prejudice resulted. This holding is unprecedented. *See*: *Easton v. City of Boulder, CO*, 776 F.2d 1441 (10th Cir. 1985) cert. den. 107 S.Ct. 71 (1985); *United States Gypsum Co. v. Schiazo Bros. Inc.*, 668 F.2d 172 (3d Cir. 1981); *Franklin Music v. American Broadcasting Companies*, 616 F.2d 528, (3d Cir. 1979); *Response of Carolina, Inc. v. Leasco Response, Inc.*, 537 F2d 1307 (5th Cir. 1976); *Kisteneff v. Tiernan*, 514 F.2d 896 (1st Cir. 1975).

Plaintiffs ask this Court to define the burden to be met to establish abuse of discretion as a showing that "any" prejudice resulted, and not that "undue" prejudice resulted.

II. WHERE PLAINTIFFS ARE ARBITRARILY EXCLUDED FROM THE TRIAL OF THEIR CASE, WITHOUT THE BENEFIT OF A HEARING, PLAINTIFFS ARE DENIED THEIR RIGHTS OF DUE PROCESS AS GUARANTEED BY THE FIFTH AND SEVENTH AMENDMENTS TO THE CONSTITUTION.

A. A PLAINTIFF MAY NOT BE EXCLUDED FROM HIS OR HER OWN TRIAL WITHOUT A HEARING COMPLYING WITH THE REQUIREMENTS OF PROCEDURAL DUE PROCESS.

By order dated February 19, 1985, the trial court barred all plaintiffs having visible birth defects and all plaintiffs under the age of ten from the courtroom during trial. The court's decision was made upon motion of defendant. At the hearing on defendant's motion, the court did not observe even one of the injured plaintiffs it was contemplating excluding from the courtroom and heard no evidence from defendant other than counsel's mere assertion that the presence of such plaintiffs would prejudice the jury and/or cause possible disruption or distraction. At the time of the issuance of the court's order, the court did not state any specific reason as to why the mere presence of a child with a visible birth defect, of whatever age, would unduly prejudice the jury and prevent or substantially impair the jury from performing its duties. However, in the court's order denying plaintiffs' Motions for a J.N.O.V. and a New Trial the court states that the mere presence of a child with visible defects would be "inherently prejudicial."

On appeal, plaintiffs argued that by barring all visually deformed children, of any age, from the courtroom, without a hearing meeting the requirements of procedural due process, the trial court deprived plaintiffs of their right to due process as secured by

the due process clause of the Fifth Amendment, caused prejudice to the plaintiffs, and contributed to the inappropriate abstraction of matters before the jury.

In support of plaintiffs' argument, plaintiffs relied upon *Helminski v. Ayerst Laboratories*, 766 F.2d 208 (6th Cir. 1985), *cert. denied*, 474 U.S. 981 (1985), wherein the Court of Appeals for the Sixth Circuit held that a plaintiff may not be arbitrarily excluded from the courtroom without the benefit of an opportunity to be heard and seen, that a plaintiff, whether child or adult, has a presumptive right to be present at all stages of a trial and that this right may be abrogated only in the presence of an overwhelming reason to the contrary and then only in a manner consistent with due process, and that to make such a decision without first observing or speaking to such plaintiff is a violation of the principles of due process requiring a reversal and new trial.

The court of appeals refused to apply *Helminski v. Ayerst Laboratories, supra*, in the instant case upon the basis that inasmuch as its opinion in *Helminski* was not rendered until the Bendectin trial had concluded and was a case of first impression in the circuit, the court would not apply *Helminski* retroactively.

Helminski was not unprecedented. The decision was a continuation and affirmation of prior case law setting forth principles of procedural due process. See *Mathews v. Eldridge*, 424 U.S. 319 (1976), *Fillipon v. Albion Vein Slate Co.*, 250 U.S. 76 (1919); *Drayton v. Jiffee Chemical Corp.*, 591 F.2d 352 (6th Cir. 1978); *Gilday v. Board of Elections of Hamilton County, Ohio*, 472 F.2d 241 (6th Cir. 1972).

Plaintiffs ask this court to reaffirm prior to case law requiring a hearing complying with procedural due process principles before a plaintiff may be excluded from the trial of his or her own case, and to hold that the plaintiffs in the instant Bendectin case were deprived their rights of due process when they were arbitrarily excluded from the trial of their case.

B. THE PRESUMPTION IS THAT A NEWLY ANNOUNCED RULE OF LAW WILL APPLY RETROACTIVELY.

As was stated previously, *Helminski v. Ayerst Laboratories, supra,* was not unprecedented because the decision in *Helminski* was a continuation of the prior due process analysis of this instant Court, as well as the Court of Appeals for the Sixth Circuit.

However, even if *Helminski* was unprecedented, *Helminski* should be applied retroactively to the instant case. The presumption is that a newly announced rule of law will apply retroactively and the burden of persuasion to demonstrate that such an application is unjust is on the party asserting prospective-only application. *Chevron Oil Co. v. Huson,* 404 U.S. 97 (1971); *Cochran v. Birkel,* 651 F.2d 1219 (6th Cir. 1981). In the instant case, no party asserted only prospective application of the rules of law set forth in *Helminski.* Prospective application was an issue raised and decided by the court of appeals, *sue sponte.*

Plaintiffs ask this Court to apply *Helminski v. Ayerst Laboratories, supra,* retroactively to the instant Bendectin case.

III. WHERE A PLAINTIFF ALLEGES VIOLATION OF A FEDERAL STATUTE WHICH PROVIDES NO PRIVATE RIGHT OF ACTION IN HIS COMPLAINT FILED IN FEDERAL COURT, THAT ALLEGATION, ALONE, DOES NOT IMPART FEDERAL QUESTION JURISDICTION.

A. THE DECISION OF THE COURT BELOW CONFLICTS WITH THIS COURT'S DECISION IN MERRELL DOW PHARMACEUTICALS, INC. V. THOMPSON.

In *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 766 F.2d 1005 (6th Cir. 1985), the court of appeals addressed plaintiffs' cause of action alleging violation by the defendant of provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 301, *et seq.* (hereinafter FDCA) and found that plaintiffs' claim did not provide a basis for federal question jurisdiction under 28 U.S.C. Sec. 1331. The court of appeals found federal law did not create plaintiffs' cause of action because, as the parties agreed, the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the FDCA. It further found that plaintiffs' cause of action referred to the FDCA merely as one available criterion for determining whether defendant was negligent and therefore, plaintiffs' right to relief did not necessarily depend upon resolution of a substantial question of federal law. Based upon these findings, the court of appeals held that the cause of action did not arise under federal law and plaintiffs' cases were improperly removed to federal court, and ordered remand to the state court.

This Court affirmed the decision of the Court of Appeals for the Sixth Circuit, holding,

> We conclude that a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim "arising under the Constitution, laws or treaties of the United States." 28 U.S.C. Sec. 1331.

Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804 (1986) (at page 817).

Despite the foregoing, the court of appeals has not asserted that federal question jurisdiction does exist in those Bendectin cases filed in federal court by citizens of Ohio wherein a cause of action alleging violation of the FDCA is present. The court of appeals stated as follows:

> The more difficult question concerns federal jurisdiction over Ohio plaintiffs. The only basis for the plaintiffs to assert jurisdiction in this court is federal question jurisdiction. 28 U.S.C. Sec. 1331. Under 28 U.S.C. Sec. 1441(b) the defendant may remove cases to federal court only if there is federal question jurisdiction. For federal courts to exercise jurisdiction over Ohio cases, the case must "arise under" the constitution, laws or treaties of the United States. The district judge found as a result of this court's opinion in *Thompson v. Merrell Dow*, 766 F.2d at 1005, that there was no basis for federal question jurisdiction . . . We modify the district court order insofar as we find that the district court did have federal question jurisdiction

> over those Ohio plaintiffs who filed their complaints in federal court.

(App. at 12a).

> A straight forward reading of plaintiffs' complaint gives the undeniable impression that plaintiffs intended to allege an implied cause of action under FDCA.

(App. at 18a).

Thus, the court of appeals determined that merely because plaintiffs intended to allege federal court jurisdiction in the pleading of violations of the FDCA, federal court jurisdiction exists.

The decision of the court of appeals is completely contrary to this Court's holding in *Merrell Dow Pharmaceuticals, Inc. v. Thompson, supra*, and this Court must reverse the ruling of the court of appeals.

CONCLUSION

The appellate court's opinion below conflicts with this Court's long standing case law guaranteeing procedural due process in the fair and impartial trial of a litigant's case or controversy, as well as with this Court's recent decision in *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986). By its decision, the appellate court has placed unacceptable restrictions upon the due process rights of litigants and has expanded federal question jurisdiction. For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Nos. 85-3858/3876/3877

In Re: Benedectin Litigation

Sarah Ann Hoffman; et al. (85-3858),
Elizabeth Ann Davis; et al. (85-3876),
Shane Ross Wood; et al. (85-3877),
Plaintiffs-Appellants,

v.

Merrell Dow Pharmaceuticals, Inc., (formerly known as) Richardson-Merrell, Inc.,
Defendant-Appellee.

Before : ENGEL, Chief Judge*; and JONES and NELSON, Circuit Judges.

AUG 30,1988

JUDGMENT

ON APPEAL from the United States District Court for the Southern District of Ohio.

THIS CAUSE came on to be heard on the record from the said district court and was argued by counsel.

ON CONSIDERATION WHEREFOF, It is now here ordered and adjudged by this court that the judgment of the said district court of August 27, 1988 be and the same is hereby affirmed in part; vacated in part, and these cases remanded with instructions; the portion remanding all cases brought by Ohio citizens originally in state courts is not disturbed; those thirteen cases brought by Ohio citizens in federal court over which it is conceded there is no federal jurisdiction shall be dismissed without prejucdice.

Each party is to bear its won cost on appeal.

ENTERED BY ORDER OF THE COURT

Leonard Green, Clerk
/s/Leonard Green

Clerk

*The Honorabel Albert J. Engel assumed the duties of Chief Judge effective April 1, 1988.

Issued as Mandate:
COSTS:

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Deputy Clerk

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Nos. 85-3858/3876/3877

In Re: Benedectin Litigation

Sarah Ann Hoffman; et al. (85-3858),
Elizabeth Ann Davis; et al. (85-3876),
Shane Ross Wood; et al. (85-3877),
Plaintiffs-Appellants.

v.

Merrell Dow Pharmaceuticals, Inc., (formerly known as) Richardson-Merrell, Inc.,
Defendant-Appellee.

Appeal from the United States District Court for the Southern District of Ohio.

Decided and Filed August 30, 1988

Before: ENGEL, Chief Judge;* JONES and NELSON, Circuit Judges.

ENGEL, Chief Judge, delivered the opinion of the court, in which NELSON, Circuit Judge, joined. JONES, Circuit Judge, (pp. 72-79) delivered a separate opinion concurring in part and dissenting in part.

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*The Honorable Albert J. Engel assumed the duties of Chief Judge effective April 1, 1988.

ENGEL, Chief Judge. These actions were brought on behalf of children with birth defects against Merrell Dow Pharmaceuticals, Inc., alleging that their birth defects were caused by their mothers' ingestion during pregnancy of defendant's anti-nausea drug Bendectin. Immediately involved are eleven hundred eighty claims in approximately eight hundred forty-four multidistrict cases.[1] These cases represent only a part of the Benedictin cases which have been brought in numerous federal and state courts around the nation.[2] Although there are some differences among the complaints, most are virtually identical, requesting relief on the grounds of negligence, breach of warranty, strict liability, fraud, and gross negligence, and asserting a rebuttable presumption of negligence per se for defendant's alleged violation of the misbranding provisions of the federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*

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[1] The discrepancy between the number of claims and number of cases is due to some case numbers containing more than one family and some plaintiffs having filed lawsuits in both state and federal court.

[2] *See, e.g., Merrell Dow Pharmaceuticals, Inc., v. Thompson* 106 S. Ct. 3229 (1986); *Richardson-Merrell Inc., v. Koller*, 472 U.S. 424 (1985); *Watson v. Merrell Dow Pharmaceuticals, Inc.*, 769 F.2d 354 (6th Cir. 1985); *Dowling v. Richardson-Merrell, Inc.*, 727 F.2d 608 (6th Cir. 1984); *Mekdeci, by and through Mekdeci v. Merrell National Laboratories*, 711 F.2d 1510 (11th Cir. 1983); *Shelhamer v. Merrell Dow Pharmaceuticals, Inc.*, Civ. A. No. 87-0782 (W.D. Pa. 1987); *Engel v. Merrell Dow Pharmaceuticals, Inc.*, No. Civ. 83-1189E (E.D.N.Y. 1987); *Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799 (D.D.C. 1986); *Lynch v. Merrell-National Laboratories*, 646 F.Supp. 856 (D. Mass. 1986), *aff'd*, 830 F.2d 1190; *Will v. Richardson-Merrell, Inc.*, 647 F.Supp. 544 (S.D.Ga. 1986); *Raynor v. Richardson-Merrell, Inc.*, 643 F.Supp. 238 (D.D.C. 1986); *Haddad v. Richardson-Merrell, Inc.*, 588 F.Supp. 1158 (N.D. Ohio 1984); *Chambers v. Merrell Dow Pharmaceuticals, Inc.*, No. C-850888 (Hamilton County, Ohio, Court of Appeals, Dec. 24, 1986); *Dralle by Dralle v. Ruder*, 148 Ill.App.3d 961, 500 N.E.2d 514 (1986); *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. 1986); *Albertson v. Richardson-Merrell, Inc.*, 441 So.2d 1146 (Fla. Dist. Ct. App. 1983).

After twenty-two days of trial on the sole question of causation, the jury answered the following interrogatory in the negative: "Have the plaintiffs established by a preponderance of the evidence that ingestion of Bendectin at therapeutic doses during the period of fetal organogenesis is a proximate cause of human birth defects?" *In re Richardson-Merrell, Inc., Bendectin Products*, 624 F. Supp. 1212, 1269 (S.D. Ohio 1985). Had the jury answered this question in the affirmative, it then would have answered a second question concerning the particular categories of birth defects that Bendectin caused when administered at therapeutic doses: musculosk-celetal defects, central nervous system defects, heart and circulatory defects, head defects, respiratory defects, gastrointestinal defects, genitourinary defects, and death. *Id.* Accordingly, the district judge entered judgment for defendant.

On appeal, plaintiffs argue that the federal district court did not have jurisdiction over actions brought by Ohio plaintiffs, actions originally filed in state courts, or actions originally filed in the federal district courts in any of the fifty states and later transferred to the United States District Court for the Southern District of Ohio. Other issues raised on appeal concern various aspects of the trial, including certain evidentiary rulings and the district court's decision to create the Plaintiffs' Lead Counsel Committee, to prevent withdrawal from the common issues trial while permitting new transfers into the case, to apply Ohio law to all plaintiffs, to trifurcate on the causation question, and to exclude visibly deformed plaintiffs.

We direct the dismissal without prejudice of those thirteen actions brought by Ohio citizens in federal court in which Merrell Dow has conceded that no federal question jurisdiction was invoked and has further conceded that the district court was therefore without jurisdiction to render judgment on the merits against those plaintiffs.[3] As to all

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[3] These cases are as follows:

other suits brought by Ohio citizens in federal courts and subject to this appeal, we hold that the district court did have federal question jurisdiction and thus the adverse jury verdict is binding on those plaintiffs. Finally, we do not disturb the district court's post-trial order remanding all cases brought by Ohio citizens in state courts back to the courts from which they were removed. In all other respects, we affirm.

I. BACKGROUND OF THE CASE

The unusually large number of individual cases involved here found their way to the United States District Court for the Southern District of Ohio in a variety of ways. Eight hundred thirty-four of these claims were filed either in the Northern or Southern Districts of Ohio, while seventy-three claims, originally filed in Ohio state courts, were removed to Ohio federal courts. Only twenty-nine of the cases were initially fixed in Ohio by Ohio citizens. The remainder included sixty-two plaintiffs from California, five from Texas, six from Pennsylvania, and sixty-six from other states or foreign countries. Two hundred seventy-

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C-1-84-0504 Joseph Glen LaPaglia et al.
C-1-83-2141
C-2-83-2140 Carrie Blue Fletcher
C-1-84-1499 Michael R. Oliver et al.
C-1-84-1500 Melissa Bill et al.
C-1-84-1501 Billy J. Watkins et al.
C-1-84-1502 Deborah A. Jones
C-1-84-1503 Aric McKee
C-1-85-0309 Kyle Dart
C-1-85-0310 Bethany Blaha
C-1-85-0311 Heather Black
C-1-85-0312 Scott Herskovic
C-1-85-0313 Victoria Sanayoa
C-1-85-0342 Lynne G. Gamble
C-2-85-0072 Mark R. Mitchell
C-1-85-0279 Michelle Meckanics

three claims were filed or removed to federal district courts outside Ohio and were transferred to the Southern District of Ohio by the Judicial Panel on Multidistrict Litigation. In addition to these cases, the Judicial Panel on Multidistrict Litigation referred, pursuant to 28 U.S.C. § 1407, forty-seven cases under MDL 486 for consolidated pretrial discovery. Between 1982 and the completion of the trial in 1985, 582 additional cases were referred by the panel and 557 cases were filed in the Southern District of Ohio.

The court designated a five-member Plaintiffs' Lead Counsel Committee to act as the counsel for all plaintiffs. After the completion of discovery, on November 16, 1983, the district court consolidated under Rule 42(a) of the Federal Rules of Civil Procedure all Bendectin cases originally filed in the Southern District of Ohio or transferred in MDL 486 from the Northern District of Ohio and set those cases for trial beginning June 4, 1984 on all common issues of liability. The original decision was to bifurcate the trial, and if the plaintiffs were successful in obtaining a verdict finding liability, the court would schedule individual damages trials. While consolidation for trial was mandated for all cases pending in federal court in Ohio, the trial judge also permitted consolidation upon the liability issues for any case which had been transferred to the Southern District of Ohio under MDL 486. 28 U.S.C. § 1404. Those cases would be returned to the originating district if the verdict in the first portion of the bifurcated trial was for plaintiffs. The district judge indicated that under *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), all claims which had been originally brought or removed to federal court in Ohio would necessarily be governed by Ohio law, and that plaintiffs who had originally filed in other districts and who voluntarily chose to participate in the common issues trial would consent to application of the law of Ohio by so agreeing to participate. A number of plaintiffs chose to leave the consolidated proceedings after the completion of discovery and this order, and the district court accord-

ingly returned those suits to the district in which they had been originally filed.[4]

In this order, the judge continued to allow additional plaintiffs to "opt in" to the trial, whether they had filed originally in the Southern District of Ohio or had filed in other districts and wished to have their cases transferred pursuant to 28 U.S.C. § 1404, so that by the date opt-ins were barred on March 1, 1985,557 cases originating in the Southern District of Ohio and 261 transferred cases were subject to the jury decision. A total of 368 cases assigned by the Judicial Panel on Multidistrict Litigation did not go to trial, either because of failure to opt in or because they were otherwise disposed of. One set of plaintiffs who opted in after the district court ordered a bifurcated trial on the issues of liability and damages were the *Davis* plaintiffs, who had originally filed in Arizona federal court, and who opted into the joint liability trial on February 1, 1984.

The district court asked counsel to stipulate as to all common issues of liability that could be tried during he first phase of the trial. Defendant suggested a trial only on the issue of whether Bendectin was an unreasonably dangerous product imposing upon Merrell Dow a duty to warn about such dangers. It argued that substantive law differences among the various jurisdictions represented by plaintiffs prevented consolidation as to any other issues, regardless of whether the cases had been originally filed in Ohio or had been subsequently transferred there. The plaintiffs requested a trial of all common interrelated issue of law and fact, including whether Bendectin increased the risk of birth defects in the children of pregnant mothers who ingested the drug. They also indicated that the liability issues were inextricably interwoven and needed to

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[4] *See, e.g., McFeggan v. Merrell Dow Pharmaceuticals, Inc.*, No. 87 C 70 (N.D. Ill. 1987); *Whelan v. Merrell Dow Pharmaceuticals, Inc.*, Civ. A. No. 83-3108 (D.D.C. 1987).

be tried together with causation. Because the parties could not agree which issues should be tried during the first phase of trial, the court itself decided that the common issues to be tried beginning on June 11, 1984, would be whether: (1) taken as prescribed, Bendectin caused any of a list of birth defects; (2) Bendectin was unreasonably dangerous as defined by Ohio courts; and (3) Merrell Dow provided to the medical profession adequate warnings of the danger of the product. On April 12, 1984, the district court amended this order. Rather than bifurcating the trial on issues of liability and damages, the court instead decided to trifurcate the case, or bifurcate the liability question into liability and causation. Initially, a jury determination would be made on the causation question. If plaintiffs prevailed on the causation question, the jury would then consider the other liability questions. Conversely, if defendant received a favorable verdict on the causation issue, the trial would cease. Because the case would now be trifurcated rather than bifurcated, the district judge allowed any plaintiffs whose cases had been brought originally in courts outside Ohio to rescind their agreement to participate in the trial, provided that they notify the court of their decision by May 1, 1984.

After a jury had been selected for the June 1984 trial, settlement negotiations between the parties reached a successful conclusion. The district judge certified a class for purposes of settlement. However, on appeal, another panel of this court held that class certification was inappropriate and issued a writ of mandamus vacating the district court's order. *In Re Bendectin Product Liability Litigation*, 749 F.2d 300 (6th Cir. 1984).

On December 19, 1984, the district court then rescheduled the trial to begin in February, 1985 and ordered that it proceed in the same manner and with the same issues as had been indicated in the trifurcation order of April 1984. The district judge then said that while, as before, cases originally brought in Ohio would necessarily be part

of the common issues trial, new cases originating in any other district and transferred under MDL 486 would have the option of electing to participate in the February 1985 trial, provided the plaintiffs did so by February 1, 1985. The court would not allow any plaintiff whose case has been filed in any state other than in Ohio and had been voluntarily consolidated in the common issues trial prior to the date of that order, December 19, 1984, to rescind the decision to participate.

The trifurcated trial commenced in February, 1985. Fearing undue prejudice to defendant, the trial judge, without actually viewing any plaintiffs, granted defendant's motion *in limine* to exclude all visibly deformed plaintiffs as well as all plaintiffs below the age of ten, whether or not they displayed birth defects. In another room in the courthouse, the court provided video arrangements to enable any excluded plaintiff to view the course of trial, as well as communications equipment so that plaintiffs could assist counsel. Further, the jurors and the deformed plaintiffs used different elevator banks so as to preclude the possibility of even accidental contact. Following trial, judgment was entered for defendant upon the jury's negative answer to the question whether plaintiffs had proven that ingestion of Bendectin proximately causes birth defects.

On August 27, 1985, after the entry of judgment and during the pendency of plaintiffs' motion for judgment NOV or new trial, the district court issued an order concerning its jurisdiction over those plaintiffs who were citizens of Ohio. This order was prompted by litigation involving two foreign plaintiffs whose claims were before the district court but are not before us on this appeal. In that related litigation, the defendant had sought to dismiss, on the ground of forum *non conveniens*, two cases which Merrell Dow had removed to the Southern District of Ohio from state courts in Ohio. The plaintiffs opposed this motion, and instead filed a motion to remand under 28 U.S.C.

§ 1447(c) for lack of subject matter jurisdiction, as the district court would not have had original jurisdiction to hear the cases under its grant of federal question jurisdiction. The trial judge granted defendant's motion to dismiss, but this court reversed, *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 766 F.2d 1005 (6th Cir. 1985), *aff'd*, 106 S. Ct. 3229 (1986). The parties agreed that the FDCA did not crete a private right of action for its violation, and our court said that federal question subject matter jurisdiction would thus exist only if the plaintiffs' right to relief depended "necessarily" on a substantial question of federal law. Finding that recovery would not "necessarily" be barred by a failure to establish a violation of the FDCA, we held that Plaintiffs' motion to remand to state court should have been granted on the ground that the district court did not have federal question jurisdiction.[5] Similarly, in this case, reasoning that Merrell Dow's status as an Ohio citizen prevented removal on the basis of diversity jurisdiction in cases brought in state court by Ohio residents, 28 U.S.C. § 1441(b), and that there was no subject matter jurisdiction over Ohio plaintiffs' complaints alleging causes of action under the FDCA because the statute does not create an implied right of action, the district court remanded all complaints brought by Ohio plaintiffs in Ohio state courts under 28 U.S.C. § 1441(c) and dismissed without prejudice the Ohio resident complaints that had been brought in federal court in Ohio pursuant to 28 U.S.C. § 1331. It then issued a stay of this order pending appeal. Plaintiffs' motion for judgment NOV or new trial was denied on September 17, 1985, and these appeals followed.

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[5] On appeal the Supreme Court assumed that the FDCA did not create a private right of action but carefully avoided any definitive ruling on that question. 106 S.Ct. at 3233.

II. MATTERS AFFECTING ONLY SOME PLAINTIFFS

A. PLAINTIFFS' LEAD COUNSEL COMMITTEE

On April 30, 1982, the district judge appointed a Lead Counsel Committee, selecting only some of the plaintiffs' attorneys, but only after counsel for a majority of the plaintiffs agreed to the formation of this Committee. He gave plaintiffs' attorneys time to object or propose others to serve on it The *Wood* plaintiffs claimed that this decision denied them the right freely to choose counsel, in that the four counsel that the trial judge chose did not include their own attorney. No plaintiff responded to the district judge's order to show cause why such appointment should not be confirmed. In complex cases, it is well established that the district judge may create a Plaintiffs' Lead Counsel Committee. *Vincent v. Hughes Air West, Inc.*, 557 F.2d 759, 773-74 (9th Cir. 1977); *In Re Air Crash Disaster at Florida Everglades*, 549 F.2d 1006, 1014-15 (5th Cir. 1977); *Farber v. Riker-Maxson Corp.*, 442 F.2d 457, 459 (2d Cir. 1971). We find no error in creating such a committee in this case, especially given the failure below to object to such a procedure.

B. JURISDICTION

For most of the plaintiffs in this case, there is no question that both the district court and this court have jurisdiction. The defendant, because it is incorporated in Delaware but has its principal place of business in Ohio, is for diversity purposes a citizen both of Ohio and Delaware, 28 U.S.C. § 1332(c), and most of the plaintiffs are citizens of other states or foreign countries. Since all of such plaintiffs allege damages of a sum exceeding $10,000, there is diversity jurisdiction over all of their cases. The more difficult question concerns federal jurisdiction over Ohio plaintiffs. The only basis for these plaintiffs to assert jurisdiction in this court is federal question jurisdiction, 28 U.S.C. § 1331. Under 28 U.S.C. § 1441(b), the defendant

may remove cases to federal court only if there is federal question jurisdiction. For federal courts to exercise jurisdiction over Ohio cases, the cases must "arise under" the constitution, laws or treaties of the United States. The district judge found as a result of this court's opinion in *Thompson v. Merrell Dow*, 766 F.2d at 1005, that there was no basis for federal question jurisdiction. Accordingly, he dismissed without prejudice cases originally filed by Ohio residents in Ohio federal court, and remanded to state court those cases which had been originally filed in Ohio state courts and removed by defendant.

We modify the district court order insofar as we find that the district court did have federal question jurisdiction over those Ohio plaintiffs who filed their complaints in federal court. Thus, with the exception of those few cases noted *infra*, the Ohio plaintiffs who initially brought suit in federal court and went to trial on the issue of causation are bound by the jury's verdict. As to them, Merrell Dow is entitled to the entry of judgment on the merits in its favor. An exception exists for those thirteen cases filed by Ohio plaintiffs' in federal court which are properly conceded by defendants not to allege any substantial federal question in their complaints. In all other respects, we affirm.

In explanation of the above holding, it is necessary first to consider whether the district court had jurisdiction over those Ohio citizens who filed their original actions in federal court. The crux of this inquiry necessarily turns on whether these plaintiffs alleged a substantial federal question in their complaints. Absent diversity there was, as noted earlier, no basis other than the allegation of a federal question for the trial court to exercise authority over these controversies.

Although more than 800 complaints were filed and consolidated in this appeal, many of the causes of action are identical among the complaints. In the typical complaint,

the first cause of action sounds in negligence; the second cause of action is for breach of warranty; the third pleads strict liability; and the sixth alleges willful and wanton behavior. There is no question that these four causes of action are completely state created and do not support federal question jurisdiction. The fourth and fifth causes of action are the only two that could possibly be considered federal causes of action. Typical is the complaint in *Basalyga v. Merrell Dow Pharmaceuticals, Inc.*, No. C-1-84-1497. That complaint alleges jurisdiction based on both federal question and diversity jurisdiction:

FOURTH CAUSE OF ACTION

> 17. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 16 and for their Fourth Cause of Action state as follows.
>
> 18. That the applicable Federal law covering the manufacturing and distributing of drugs during the time period in controversy was the Federal Food, Drug and Cosmetics [sic] Act passed by the 7th [sic] Congress on June 25, 1938, and cited as 52 Stat 1040, as amended.
>
> 19. That the purpose of 52 Stat 1040, among other purposes, was to prohibit the movement in Interstate Commerce of misbranded drugs.
>
> 20. That per § 201(n) of 52 Stat 1040, the determination as to whether a drug is misbranded includes "not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences, which may result from the use of the article to which the labeling relates under the conditions of use prescribed in

the labeling thereof, or under such conditions of use as are customary and usual."

21. That Defendant did not at any time during the time period in controversy, reveal or attempt to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug in question for indications relating to pregnancy.

22. That pursuant to § 502(a) of 52 Stat 1040, a drug is deemed misbranded if its labeling is false or misleading in any particular.

23. That pursuant to § 502(f)(2) of 52 Stat 1040, a drug is deemed misbranded unless its labeling bears "such adequate warning against use in those pathologic conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods, or duration of administration or application, in such manner and form, as are necessary for the protection of users."

24. That pursuant to § 502(j) of 52 Stat 1040, a drug is deemed misbranded if it is "dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended or suggested in the labeling thereof."

25. That the promotion of said drug, Bendectin, by the Defendant for the use in females during the time period in controversy, without revealing or attempting to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug, constituted misbranding of said pharmaceutical drug per subsections (a), (f)(2) and (j) of § 502 and (n) of § 201 of 52 Stat 1040.

26. That violation of said Federal Statutes in the promotion of said drug, Bendectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by said Minor Plaintiffs and directly and proximately caused and will cause said Minor Plaintiffs to suffer considerable pain and suffering and to undergo continuous medical treatment, and the Adult Plaintiffs, as parents of the Minor Plaintiffs, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which the Adult Plaintiffs, as Next Friends and Guardians of the Minor Plaintiffs, have been damaged in the amount of **Ten Million ($10,000,000.00) Dollars** compensatory damages, and the Adult Plaintiffs Individually, have been damaged in the amount of **Five Million ($5,000,000.00) Dollars** compensatory damages.

FIFTH CAUSE OF ACTION

28. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 27 and for their Fifth Cause of Action state as follows.

29. The Defendant has made false and fraudulent representations of fact as to the safety, nontoxicity, and freedom from side effects of its product Bendectin and those representations were made under circumstances that the said Defendant knew or should have known that they were false, ore alternatively, were represented to be true while said Defendant had no knowledge as to the truth thereof and the said Defendant stood to benefit financially by its misrepresen-

tations, active and constructive. These representations were made in promotional literature, product inserts and by detailmen to prescribing physicians. By these representations the Defendant worked a fraud and deceit upon the consuming public, and more particularly, upon the Plaintiffs.

30. The Defendant deliberately pursued a policy of non-disclosure with regard to adverse reactions attributable to the product Bendectin, especially, but not limited to, a number of reporting physicians, each reporting that a number of mothers who used Bendectin during pregnancy gave birth to physically deformed babies. The said Defendant thereby deprived the medical community and the public and the Plaintiffs of significant facts which, if known, would have permitted an informed judgement [sic] of the drug in light of the grave risks attending its use.

31. The Defendant failed to submit all relevant data bearing on the safety of the drug Bendectin to the Food and Drug Administration, as required by law.

32. That the acts and omissions of the Defendant, as aforementioned, directly and proximately caused the injuries suffered by said Minor Plaintiffs and directly and proximately caused and will cause said Minor Plaintiffs to suffer considerable pain and suffering and to undergo continuous medical treatment, and the Adult Plaintiffs, as parents of the Minor Plaintiffs, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which the Adult Plaintiffs, as Next Friends and Guardians of the Minor Plaintiffs, have been damaged in the amount of **Ten Million**

> **($10,000,000.00) Dollars** compensatory damages, and the Adult Plaintiffs Individually, have been damaged in the amount of **Five Million ($5,000,000.00) Dollars** compensatory damages.

Merrell Dow argues that plaintiffs employing this language did in fact allege a substantial federal claim based on an implied private right of action under the FDCA, even though later developments in the federal case law might have led to a contrary conclusion. Following a careful examination of the complaints and the record, including portions of the trial memorandum and pretrial conference transcript cited by plaintiffs, we agree. A straightforward reading of plaintiffs' complaints gives the undeniable impression that plaintiffs intended to allege an implied cause of action under the FDCA. As the Basalyga's complaint states: "This Court has jurisdiction based on [28 U.S.C. § 1331] inasmuch as liability arising under a federal statute is alleged. . . .The Defendant failed to submit all relevant data bearing on the safety of the drug Bendectin to the Food and Drug Administration, as required by law, [which]. . .directly and proximately caused [plaintiffs'] injuries." Identical or similar express assertions of section 1331 jurisdiction appear in most if not all of the complaints in question. Moreover, unlike the parties in *Merrell Dow v. Thompson,* 106 S. Ct. at 3233; 106 S. Ct. at 3241 n.4 (Brennan, J., dissenting), the parties in the instant suit never conceded that there was no implied cause of action under the FDCA. In fact, contrary assertions were made by some of plaintiffs' counsel at various points during trial. Although strategically it may be profitable for plaintiffs' counsel now to argue that they never intended to plead an implied cause of action, the language of their complaints leads to an opposite conclusion. These plaintiffs went to trial in federal court intending to take full advantage of any ruling that an implied cause of action existed, no doubt intending as well to take advantage of a favorable verdict

on the issue of causation if the jury could be persuaded by the evidence to return it.

In summary, we have concluded that, with the exception of the thirteen cases previously noted, all Ohio plaintiffs who originally filed their actions in federal court intended to invoke federal question jurisdiction based, at least in part, on an implied cause of action under the FDCA. It is also evident that under existing case law a sufficient basis for section 1331 jurisdiction existed to make binding on those plaintiffs the adverse verdict which actually resulted.

As the case law indicates, a substantial federal question is presented as long as the pleadings invoking federal question jurisdiction are not "so attenuated and unsubstantial as to be absolutely devoid of merit," "wholly insubstantial," "obviously frivolous," "plainly unsubstantial," or "no longer open to discussion." *Hagans v. Lavine*, 415 U.S. 528, 536-37 (1974) (quoting *Newburyport Water Co. v. Newburyport*, 193 U.S. 561, 579 (1904); *Bailey v. Patterson*, 369 U.S. 31, 33 (1962); *Hannis Distilling Co. v. Baltimore*, 216 U.S. 285, 288 (1910); *Levering & Garrigues Co. v. Morrin*, 289 U.S. 103, 105 (1933); and *McGilvra v. Ross*, 215 U.S. 70, 80 (1909)). *See Mt. Healthy City School District Board of Education v. Doyle*, 429 U.S. 274, 279 (1977) ("jurisdiction is sufficiently established by *allegation* of a claim under the Constitution or federal statutes, unless it 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction' ") (emphasis added, citations omitted). The standard "is easily met—an *arguably* plausible claim must be allowed to proceed." *Robbins v. Reagan*, 780 F.2d 37, 43 (D.C. Cir. 1985) (emphasis added). The test, according to Wright and Miller, is "whether there is *any* legal substance to the position the plaintiff is presenting." 13B C. Wright, A. Miller & E. Cooper, *Federal Practice and Procedure* § 3564, at 67 (2d ed. 1984) (emphasis added, footnote omitted). Until this court or the Supreme Court holds that there is no implied private right

of action under the FDCA, the opposite position cannot be deemed either frivolous or unsubstantial.

A different analysis, however, may apply to those Ohio plaintiffs who originally brought suit in state courts. Since these plaintiffs invoked the jurisdiction of state and not federal court, it is perhaps unlikely, even where the language might arguably include an implied cause of action under the FDCA, that these plaintiffs intended to plead such a cause of action.[6] In any case, even had the Ohio citizens filing in state court intended to plead an implied cause of action under the FDCA, 28 U.S.C. § 1447(d) precludes this court from reviewing the district court's remand on direct appeal. *Gravitt v. Southwestern Bell Telephone Co.*, 430 U.S. 723 (1977) (per curiam).[7]

Finally, defendant has conceded that thirteen cases filed by Ohio citizens in federal court are unique insofar as these plaintiffs failed to allege any substantial federal question in their complaints. *See* cases listed *supra* note 3. Since no federal question is alleged, we dismiss these thirteen cases without prejudice for lack of federal jurisdiction. Fed. R. Civ. P. 12(b)(1).

In summary, the thirteen cases brought by Ohio plaintiffs in which it is conceded that no federal question was alleged are dismissed without prejudice; and the cases brought by Ohio plaintiffs in federal court must be considered on the merits since we hold that the district court did have federal question jurisdiction.

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[6] While the same logic would appear to apply to any cases brought by Delaware citizens in state court given Merrell Dow's status as a Delaware citizen due to its incorporation in that state, 28 U.S.C. § 1332(c), we are aware of no such cases brought before the district court and our attention has been called to none.

[7] Review might be possible by way of mandamus, but no mandamus proceedings have been instituted.

C. DAVIS PLAINTIFFS' DECISION TO OPT OUT

The *Davis* plaintiffs make the argument that they, too, are not bound by the district court judgment. Originally, these four plaintiffs brought suit in Arizona federal court. On February 1, 1984, these plaintiffs chose to participate in the joint trial in the Southern District of Ohio. On December 19, 1984, the district court, while allowing additional plaintiffs to opt in to the consolidated trials until February 1, 1985, ruled that previous decisions by out-of-state plaintiffs to participate in the common issues trial would be deemed binding. On January 25, 1985, these plaintiffs sought to opt out of the joint issues trial. The district court, consistent with its December 19 order, refused to allow plaintiffs to do so. Judgment was thus entered against them when the jury returned the verdict for defendant, despite their having indicated a desire to opt out. No doubt these parties would have fought to stay in had the jury finding been favorable to them.[8]

After the jury verdict, these defendants filed a motion to set aside the judgment because of their earlier expressed desire to opt out. The grounds for this motion were that the court could not enter judgment against them as a result of a trial that they had participated in without their consent. They argued that their decision to opt out was based on changes in the manner in which the court planned to try the common issues trial, including the exclusion of visibly deformed plaintiffs, trifurcation, prohibition of references to Thalidomide, and other issues of which they were not informed before the court's December 19 order making their previous election to participate binding. The district court denied this motion, in part because

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[8] We make this observation merely to point out the critical need, so evident here, that the decisions in this appeal be principled and uninfluenced by the hindsight of what later transpired. A different result by the jury undoubtedly would have reversed the position on appeal of all the parties.

each of these plaintiffs had an opportunity to withdraw after the court changed its decision to trifurcate rather than bifurcate the case in May of 1984. The court also rejected plaintiffs' other arguments. These included some statements regarding the exclusion of plaintiffs that the court denied were ever made, and on the exclusion of references to Thalidomide. The plaintiffs could not have been ignorant of these matters when they made their decision to stay in the case after 1984. The district judge also noted that plaintiffs cited no legal authority to support their claim of entitlement to a second opportunity to opt out.

On appeal, these plaintiffs argue that had the court enabled them to opt out, the defendant would have suffered no prejudice. Therefore, it was an abuse of discretion for the district judge to refuse to allow them to opt out, especially since the court was willing to allow new plaintiffs to enter into the case after the opt-out date. Thus, the district judge would not know until after the opt-in process subsequently ceased, indeed until the trial itself, how many plaintiffs would be participating. The plaintiffs also argue that in the particular case of Davis, his alleged defect was dwarfism, which was not one of the specific defects the jury was to address if it found for plaintiffs on the first issue. This argument was raised for the first time in this appeal. It is in all events mooted by the jury's verdict that Bendectin did not cause any birth defects. Further, Davis continued to participate long after Judge Rubin indicted which specific defects the jury would decide Bendectin caused. Judge Rubin in fact provided these plaintiffs an opportunity to opt out of the trial after the trifurcation decision was made and held the option open for an additional eight months and until only a few months before the trial. Under such circumstances we cannot find that they district judge abused his discretion in denying this untimely motion.

The *Davis* plaintiffs also argue that the district judge could not apply Ohio law to them, because, since their complaints had been brought in Arizona federal court, only Arizona law could govern them. They maintain it would be impermissible to allow the court's procedural rule denying their opting out to cancel their substantive right to have the law of Arizona apply. Similarly, the *Wood* plaintiffs argue that the district court was required to apply the law of Texas to their claims. Although the *Wood* plaintiffs never filed a petition to opt out at any time, they argued that they should have been able to opt out because the district court could not apply Ohio law in deciding their claims. These arguments are not jurisdictional. If correct, the *Davis* and *Wood* plaintiffs would be entitled to a new trial, not dismissal. Further, the choice of law question applies to all non-Ohio plaintiffs. We therefore defer consideration of this conflict of laws argument to the next section.

III. GOVERNING LAW OF PROXIMATE CAUSATION IN CONFLICT OF LAWS CONTEXT

Before determining whether proximate causation should properly be considered a separate issue for purposes of Rule 42(b), it is necessary first to determine under which jurisdiction's law of proximate causation we are operating. At trial, Judge Rubin applied the substantive law of Ohio to any case brought in Ohio, citing *Erie*, 304 U.S. 64, and required all plaintiffs who transferred their cases to the Southern District of Ohio under MDL 486 and 28 U.S.C. § 1404 also to consent to have the liability issues tried in accordance with the substantive law of Ohio. Since the question of proximate causation was tried under the law of Ohio for all cases, and since the judge determined that the law of Ohio considered causation a separate issue from fraud, he prohibited the plaintiffs from introducing evidence that defendant had committed fraud in its submission to the FDA of test results regarding the safety of

Bendectin. Because he found that fraud, even if proved, had no relation to the causation question under Ohio law, he concluded that the trifurcated case could proceed on the separate issue of causation.

While we are in agreement with the result reached by Judge Rubin, our course of reaching that decision differs from his in one important respect which requires closer analysis. On appeal, those plaintiffs not represented by Plaintiffs' Lead Counsel Committee argue that Judge Rubin could not assign to them the burden of proof on the proximate causation question because the law of their home states would place this burden on the defendant. They argue that had the law of Ohio not been applied, and had there not been trifurcation, they could have proved a rebuttable presumption of negligence because of the defendant's violation of the FDCA, and the proof of that statutory violation would shift to the defendant the burden of proof regarding causation. They also argue that, as under Ohio law, the law of their home states would shift the burden of proof because of defendant's fraud. The alleged fraud they assert consisted of defendant's failure to report to the FDA the results of animal and human studies concerning Bendectin's propensity to cause birth defects. Even if Ohio law did not recognize this doctrine, it is argued by the *Wood* plaintiffs that the district judge was obligated to apply the law of Texas because Ohio's choice of law rules dictate that Texas law governs their claims, notwithstanding that the *Wood* plaintiffs originally filed their case in Ohio federal court. Since the law of Texas does not consider causation and liability to be separate issues in this type of case, they argue that the district court abused its discretion in trifurcating the claims brought by these Texas plaintiffs. They ask us to allow them to opt out of the common issues trial, presumably permitting them to have their case transferred to Texas and tried under the law of Texas, with the burden of proof upon the defendant.

The *Davis* plaintiffs, who filed originally in other states and then transferred their cases to the multidistrict litigation in the Southern District of Ohio, raise a slightly different argument. Rather than merely arguing, as do the *Wood* plaintiffs, that the district court could not force them to have their cases tried by the law of any state other than that which the conflicts rules of Ohio dictate, they assert that the district judge could not require that they submit to the law of any state other than that where the complaint was originally filed. The *Davis* plaintiffs claim that the law of Arizona should govern their case, and that since the district judge applied Ohio law, their case should be returned to Arizona to be tried under the law of Arizona, with the burden of proof upon the defendant in at most a bifurcated trial.

In response, defendant contends that the plaintiffs never argued at trial that they could not prove that Bendectin caused birth defects because the defendant concealed evidence of teratogenicity.[9] Rather, defendant asserts that plaintiffs' argument was that the evidence was sufficient to prove that the drug caused all varieties of births defects. Likewise, at trial the plaintiffs' own proposed instructions placed the burden of proof on themselves, contrary to lead counsel's assertion on appeal. Further, the plaintiffs themselves urged the district judge to apply the law of Ohio to this case, and never argued that any other law should apply. Those plaintiffs who transferred into the common issues trial had the unfettered discretion to accept the Ohio forum and the district court's previously announced decision to apply Ohio law, or to return their cases to the district in which they were originally filed.

We agree with Judge Rubin's conclusion that under Fed. R. Civ.P. 51 any objections that the instructions on caus-

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[9] Teratogenic is defined as: "Tending to produce deformities of the body, especially teratism; causing the development of monsters or monstrosities (deformed fetuses or infants)." 4 *Smidt's Attorneys' Dictionary of Medicine* T-33 (1986).

ation were not couched in terms of Arizona or Texas law were waived when not made before they jury retired. Even if such a claim were construed as plain error, we observe that there was no showing that the law of these states differed in any material respect from that of Ohio. Out of caution, however, we inspect this issue more closely.

The Supreme Court has long held that a federal district court exercising diversity jurisdiction must apply the same conflict of laws rules that the state court would apply.

> The conflict of laws rules to be applied by the federal court in [a state] must conform to those prevailing in [that] state['s] courts. Otherwise, the accident of diversity of citizenship would constantly disturb equal administration of justice in coordinate state and federal courts sitting side by side. . . . Any other ruling would do violence to the principle of uniformity within a state, upon which the *Tompkins* decision is based.

Klaxon Co. v. Stentor Electric Manufacturing Co., 313 U.S. 487, 496 (1941) (citations omitted). "[T]he conflict-of-laws rules to be applied by a federal court in Texas must conform to those prevailing in the Texas state courts. A federal court in a diversity case is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits." *Day & Zimmermann, Inc. v. Challoner*, 4213 U.S. 3, 4 (1975) (per curiam).

Applying *Klaxon* here, it is apparent that it is Ohio's conflict of laws rules that must normally determine which substantive state law should govern the rights of the parties. Although determining what law should apply is not altogether without doubt, the Ohio Supreme Court appears to have clarified the issue substantially in this past decade. In the most recent of a series of cases, *Morgan v. Biro Mfg. Co.*, 15 Ohio St. 3d 339, 474 N.E.2d 286 (1984) (per

curiam), the Ohio Supreme Court reaffirmed its intention to abandon a strict adherence to the traditional rule of *lex loci delicti* in favor of a more flexible rule based on which state has "a more significant relationship to the lawsuit," *id.* at 289, in light of the factors set forth in section 145 of 1 *Restatement (Second) of Conflict of Laws* § 145 (1971).[10] *Morgan* involved a product liability action against the manufacturer of a meat grinder. There the court concluded that even though the product was manufactured in Ohio and the defendant manufacturer was incorporated in Ohio, Kentucky had the most significant relationship to the parties since that is the state where the injury occurred, the plaintiff resided, and the workers' compensation benefits were determined, and Kentucky was the state responsible for inspection of the condition and safety of the product for use in that state. As a basis for its holding, the court quoted both section 145 and section 6,[11] as incorporated

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[10] Section 145 provides:

(1) The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence of the parties under the principles stated in § 6.

(2) Contacts to be taken into account in applying the principles of § 6 to determine the law applicable to an issue include:

(a) the place where the injury occurred,

(b) the place where the conduct causing the injury occurred,

(c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and

(d) the place where the relationship, if any, between the parties is centered.

These contacts are to be evaluated according to their relative importance with respect to the particular issue.

[11] Section 6 states:

(1) A court, subject to constitutional restrictions, will follow a

in section 145, of the Restatement of Conflicts. It is thus apparent that the Supreme Court of Ohio recognizes the limitations of the *lex loci delicti* rule that are imposed by the broader considerations of sections 145 and 6 of the Restatement, since it quotes both of these sections in full. *Morgan,* 474 N.E.2d at 289 n.56.

Applying here the flexible approach adopted in recent Ohio case law and codified in sections 145 and 6 requires an inquiry into which state possesses the most significant relationship. If this question cannot be determined, the law of the place of the injury controls. *Id.* at 289; 1 *Restatement (Second) of Conflict of Laws* § 146 (1971).

Throughout this litigation there has been some discussion of the law of states in which non-Ohio plaintiffs are domiciled. We, however, see the law of the state of manufacture of the product as being more significant in this type of case than that of the state where an individual plaintiff happens to live. Merrell Dow manufactured and distributed a uniform drug internationally. The company issued a uniform set of warnings and instructions for use. The regulations governing the labeling, research, and dis-

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statutory directive of its own state on choice of law.

(2) When there is no such directive, the factors relevant to the choice of the applicable rule of law include.

(a) the needs of the interstate and international systems,

(b) the relevant policies of the forum,

(c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,

(d) the protection of justified expectations,

(e) the basic policies underlying the particular field of law,

(f) certainty, predictability and uniformity of result, and

(g) ease in the determination and application of law to be applied.

tribution of the drug were governed either by Ohio law or by the federal Food, Drug and Cosmetic Act. Standards against which defendant's wrongful or negligent conduct may be measured are also set by Ohio and federal law.

In contrast, plaintiffs seem to allege either that their domicile states have a more substantial interest in the outcome of this litigation or that no state has a particularly substantial interest, and thus the law of the state of the place of injury should prevail. Both of these arguments fail, however. Domicile states do have a strong interest in the protection and well-being of their citizens, and the Restatement plainly regards domicile as one consideration in determining the existence of a substantial state interest. *See id.* § 145. Those plaintiffs who seek to apply the law of their state of domicile may also do so on the assumption that this is where the injury occurred. Such an assumption, however, is not at all clear, for the state of domicile at the time of suit may bear little or no relation to where a mother may have taken a morning sickness drug years before. A plaintiff presently residing in Arizona, for example, might nonetheless be found to have taken Bendectin while traveling in many different states. In short, it is difficult if not impossible to perceive any meaningful relationship to the subject matter of the lawsuit for the law of the state of domicile at the time of the suit, or the state in which the drug may have been prescribed, dispensed, ingested, or the state in which the child may have been conceived, or born. This is far different from the circumstances which led the Ohio Supreme Court to apply Kentucky law in *Morgan*. The application of the same principles which led the court to Kentucky law in *Morgan* points unmistakably to Ohio law here. The State of Ohio is responsible for regulating local aspects of the marketing, manufacture, distribution, and labeling of the drug, and thus the relationship between the parties is essentially centered in Ohio, where the tortious conduct and the safety of the product are regulated. The fact that federal regu-

lation through the FDCA impacts pervasively upon the development and approval of the drug in question tends further to minimize the significance of the law of other states and to focus emphasis upon the state of manufacture as the state in which application of the federal standards and oversight is most likely to occur.

The choice of Ohio law is even more persuasive when we apply, as we must under *Morgan*, the factors set forth in section 6 of the Restatement: "[T]he needs of the interstate and international systems"; "the protection of justified expectations"; "the basic policies underlying the particular field of law", "certainty, predictability and uniformity of result"; and "ease in the determination and application of law to be applied" provide, in our judgment, a persuasive basis for holding that the more significant relationships were those of the place of manufacture. We therefore conclude that under Ohio conflicts law as applied to the circumstances of these cases, the substantive law of Ohio was properly applied to those parties over whom the district court had jurisdiction.

One final choice of law problem, however, remains. When a defendant transfers a case to another district under 28 U.S.C. § 1404, the *Erie* doctrine requires that the court apply the *choice of law* rules of the transferor state. *Van Dusen v. Barrack*, 376 U.S. 612, 637-39 (1964). The holding of *Van Dusen* is that when a plaintiff files suit in a federal court with proper venue, and the defendant transfers it to a new federal court for convenience, the transferor state's law (including its conflicts law) applies. The Supreme Court noted that section 1404(a) was not designed to defeat the plaintiff's right to obtain the state law advantages that might accrue from the exercise of the venue privilege. *Id.* at 635. "A change of venue under § 1404(a) generally should be, with respect to state law, but a change in courtrooms." *Id.* at 639 (footnote omitted). The Court expressly reserved the question whether section 1404(a) would require the application of the law of the

transferor state when the plaintiff, rather than the defendant, seeks transfer under that statute. That is the situation here for the plaintiffs who voluntarily transferred their cases to the Southern District of Ohio after they had been originally filed in federal courts in other states.

"Although much can be said for applying the law of the transferee state when it is plaintiff who has moved, the cases increasingly seem to be applying the law of the transferor court regardless of which party moved for transfer if that court was proper in terms of venue and personal jurisdiction." 15 C. Wright, A. Miller & E. Cooper, *Federal Practice & Procedure* § 3846 at 367 (footnotes omitted). We have adopted the majority position on this issue.

> Once a plaintiff has exercised his choice of forum by selecting a permissible forum, the state law of that forum should govern the action, regardless of the wisdom of the plaintiff's selection. Thus, no matter who seeks to transfer the action to a more convenient forum under § 1404(a), the state law of the forum in which the action was originally commenced remains controlling. In this manner, the outcome in the transferee district court will be the same as the outcome would have been in the state courts of the state where the action was originally brought.
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> Accordingly, we conclude that the choice of law is dependent upon the nature of the transfer. If an action is transferred under § 1404(a), the state law of the transferor court should be applied.

Martin v. Stokes, 623 F.2d 469, 473 (6th Cir. 1980). No true conflict exists, however, where another state's choice of law rules would have applied the substantive law of Ohio to this case.

Rather than attempting to analyze the conflict of laws rules of every state in the union, we will assume that the

only state laws that could apply to any individual suit would be that of the state where the injury occurred or the plaintiff was domiciled, or that of Ohio, as those would be the only places with interests sufficient to have their law govern under prevailing conflict of laws theory. In short, the district court would not have committed error if the pertinent state choice of law rules commanded that the substantive law of Ohio apply. Likewise, if the laws of any other state were the same as Ohio's on the issue of proximate causation in this case, any error on the conflict question would be harmless, for it could not have adversely affected the court's decision of the plaintiffs' rights. Instead of analyzing each state's law, then, we consider whether the district court properly concluded that the plaintiffs must prove proximate causation in these cases under Ohio law, and then determine whether any case that the plaintiffs have cited to us, or any other source of law in other jurisdictions, holds that on the facts alleged here, proximate causation was not a separate issue. Because this issue is intimately interwoven with the challenge to the trifurcation order, we discuss it in the section that follows.

IV. TRIFURCATION

The plaintiffs challenge the district judge's decision to trifurcate this case by trying only the issue of proximate causation. They maintain that trifurcation violates their due process rights and Seventh Amendment right to trial by jury, and thus renders the decision an abuse of discretion. While defendant argues that the plaintiffs cannot raise this challenge on appeal because they made no objection to trifurcation at trial, the record supports a finding that plaintiffs timely preserved their objection to this procedure.

Plaintiffs raise many different arguments to support their claim that the district court judge abused his discretion in ordering trifurcation. First, they maintain that under the law of proximate causation as applied in this

case, causation is not an issue capable of separation from issues of defendant's fraud, wrongful conduct, or negligence. Second, they object to the ruling because: the court's trifurcation decision came as a surprise and only *after* discovery had been completed; a different jury would have heard later stages of trial; proximate cause was a particularly difficult and improper issue to be independently decided by a law jury; and trifurcation resulted in a sterile trial removed from plaintiffs' actual injuries. Third and finally, plaintiffs assert that the trifurcation ruling resulted in the exclusion of evidence that was vital to the determination of the single, causation issue.

Of all the issues on appeal, the validity of the trifurcation ruling has been most troubling to us. We reiterate that the standard of review is abuse of discretion. "[T]he district court ha[s] broad discretion to order separate trials; the exercise of that discretion will be set aside only if clearly abused." *United States v. 1071.08 Acres of Land*, 564 F.2d 1350, 1352 (9th Cir. 1977). *See also Parmer v. National Cash Register Co.*, 503 F.2d 275, 277 (6th Cir. 1974) (per curiam). "The decision whether to try issues separately is within the sound discretion of the court. . . . Abuse of discretion exists only where there is 'definite and firm conviction that the court below committed a clear error of judgment in the conclusion it reached upon a weighing of the relevant factors.' " *Yung v. Raymark Industries*, 789 F.2d 397, 400 (6th Cir. 1986) (citation omitted).

The standards for separating issues is set forth in the language of Fed. R. Civ. P. 42(b):

> The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-part claim, or of any separate issue or of any number of claims, cross-claims

> counterclaims, third-party claims, or issues, always preserving inviolate the right of trial by jury as declared by the Seventh Amendment to the Constitution or as given by a statute of the United States.

"The Advisory Committee Note to the 1966 amendment, though cryptic, suggests that. . .the changes in Rule 42 were intended to give rather delphic encouragement to trial of liability issues separately from those of damages, while warning against routine bifurcation of the ordinary negligence case." 9 C. Wright, A. Miller & F. Elliott, *Federal Practice & Procedure,* § 2388 at 280 (1971 & Supp. 1987). It cannot seriously be argued that this is a routine case.

The principal purpose of the rule is to enable the trial judge to dispose of a case in a way that both advances judicial efficiency and is fair to the parties.

> The provision for separate trials in Rule 42(b) is intended to further convenience, avoid delay and prejudice, and serve the ends of justice. It is the interest of efficient judicial administration that is to be controlling, rather than the wishes of the parties. The piecemeal trial of separate issues in a single suit is not to be the usual course. It should be resorted to only in the exercise of informed discretion when the court believes that separation will achieve the purposes of the rule.

Id. at 279 (footnotes omitted). Neither Rule 42(b) nor the textual elaboration cited gives any precise guidelines for the trial judge in considering the propriety of ordering separate trials, probably because of the wide variety of circumstances in which it might come into play. Consequently, courts have adopted a case-by-approach. "Essentially, the question is one that seems to depend on the facts of each case, a matter to be determined by the trial

judge exercising a sound discretion." *Southern Ry. Co. v. Tennessee Valley Authority*, 294 F.2d 491, 494 (5th Cir. 1961). "In deciding whether one trial or separate trials will best serve the convenience of the parties and the court, avoid prejudice, and minimize expense and delay, the major consideration is directed toward the choice most likely to result in a just final disposition of the litigation." *In re Innotron Diagnostics*, 800 F.2d 1077, 1084 (Fed. Cir. 1986) (citation omitted). Courts, including our own, have measured trial court decisions to try issues separately by whether fairness was advanced in the particular case:

> We add the caveat expressed in *Frasier v. Twentieth Century-Fox Film Corp.*, 119 F. Supp. 495, 497 (D.Neb. 1954) that separation of issues "should be resorted to only in the exercise of informed discretion and in case and at a juncture which move the court to conclude that such action will really further convenience or avoid prejudice" and observe further that "[a] paramount consideration at all times in the administration of justice is a fair and impartial trial to all litigants. Considerations of economy of time, money and convenience of witnesses must yield thereto." *Baker v. Waterman S.S. Corp.* 11 F.R.D. 440, 441 (S.D.N.Y. 1951).

Moss v. Associated Transport Inc., 344 F.2d 23, 26 (6th Cir. 1965).

In our case this same test applies to whether the decision is to try only one or more than one issue separately. Our opinion in *In re Beverly Hills Five Litigation*, 695 F.2d 207 (6th Cir. 1982), approving trifurcation on the causation question, did not indicate any different standard of review than that applicable to bifurcation nor has our research led us to authority suggesting such a distinction. While few cases appear to have been trifurcated on the

issue of causation,[12] there are nonetheless numerous cases that have tried an individual issue separately under circumstances that, had the issue been decided in favor of the plaintiff, the trial would have had more than two phases to it.[13] In affirming a trial solely on the issue of the defense of statute of limitations, *Yung v. Raymark*, 789 F.2d at 400, we quoted Wright & Miller and held that "Rule 42(b) is sweeping in its terms and allows the court, in its discretion, to grant a separate trial of any kind of issue in any kind of case." C. Wright, A. Miller & F. Elliott, *supra*, § 2389 at 284. It follows, therefore, that a decision to try an issue separately will be affirmed unless the potential for prejudice to the parties is such as to clearly demonstrate an abuse of discretion. *Beverly Hills*, 695 F.2d at 216.

Of course, the subject for review is not the abstract question of trifurcation generally, but the appropriateness of trifurcation in the context of the litigation at hand. It is to the specific facts of this case that we must apply the 42(b) standards for separating issues.

A. PROXIMATE CAUSATION AS A SEPARABLE ISSUE

Fundamental to plaintiffs' challenge of the trifurcation decision is their argument that the causation question in this case was not an issue which could be tried separately. In support of their claim, plaintiffs rely heavily on *Gasoline Products Co. v. Champlin Refining Co.*, 283 U.S. 494, 500 (1931). There, the Court held that "[w]here the practice

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[12] *See Marder v. G.D. Searle & Co.*, 630 F.Supp. 1087 (D.Md. 1986), *aff'd sub. nom., Wheelahan v. G.D. Searle and Co.*, 14 F.2d 655 (4th Cir. 1987); *Beverly Hills*, 695 F.2d at 207.

[13] *Beeck v. Aquaslide 'N' Dive, Corp.*, 562 F.2d 537 (8th Cir. 1977) (trial limited to whether defendant had manufactured the product); *Rossano v. Blue Plate Foods, Inc.*, 314 F.2d 174, 176 (5th Cir. 1963) (separate trial on issue of agency in negligence case); *Bowie v. Sorrell*, 209 F.2d 49 (4th Cir. 1953) (separate trial on question of validity of release; tried before two juries).

permits a partial new trial, it may not properly be resorted to unless it clearly appears that the issue to be retried is so distinct and separable from the others that a trial of it alone may be had without injustice." The Court noted that the issue in that case could not be submitted independently of the others without creating jury confusion and uncertainty that would "amount to a denial of a fair trial." *Id.* Many courts consider the issue's ability to be tried separately, and without injustice, to be the standard for determining whether the Seventh Amendment has been violated by conducting a trial only on that one issue. Thus, they apply the *Gasoline Products* standard to initial determinations whether a district judge properly ordered a separate trial in the first instance. *Franchi Construction Co. v. Combined Insurance Co. of America,* 580 F.2d 1, 7 (1st Cir. 1978). While *Beverly Hills* did not cite *Gasoline Products,* our court in *Helminski v. Ayerst Laboratories,* 766 F.2d 208, 212 (6th Cir. 1985), cited *Gasoline Products* as the standard for determining whether the issues of liability and damages in that case were sufficiently separable to justify a separate trial. *See also In re Innotron Diagnostics,* 800 F.2d at 1086 (separate jury trials appropriate where issues to be tried are "distinct and separable"). We affirm the appropriateness of the *Gasoline Products* standard to the context of Rule 42(b).

Under this standard, many courts have upheld cases bifurcated between liability and damages because the evidence pertinent to the two issues is wholly unrelated, and as a logical matter, liability must be resolved before the question of damages. *See* C. Wright, A. Miller & F. Elliott, *supra,* § 2390 at 296-97. By the same token, courts have refused to permit even bifurcation of liability and damages where these issues could not be tried separately. In *C.W. Regan, Inc. v. Parsons,* 411 F.2d 1379, 1388 (4th Cir. 1969), the court disapproved bifurcation because under the law of Virginia, liability and damages could not be divided

when the separate and unconnected actions of several people may have produced the total damage.

In the present case, plaintiffs argue that the *Gasoline Products* standard is violated because under the current standards and presumptions set forth in Ohio law, the issue of causation cannot be separated from the issue of defendant's tortious conduct. In their assertion of the non-separability of these two issues, plaintiffs cite various tort theories that shift the burden of proof to defendants before causation has been proven more probable than not or weaken plaintiffs' burden of proof with regard to causation.

First, plaintiffs contend that in cases involving multiple possible causes, the courts must abandon any "but for" causation test in favor of the "substantial factor" test to be applied where plaintiff seeks to prove that the defendant's wrongful act is only one of several substantial factors bringing about the injury. Thus, it is argued, because the determination of wrongdoing affects which standard plaintiffs need prove, liability must be tried either before or contemporaneously with the determination of causation. Moreover, plaintiffs argue that the court should have charged the jury that the plaintiff need only show that Bendectin is a substantial contributing factor in causing birth defects and the burden of proof would then shift to the defendant to prove that Bendectin was not such a substantial factor.

In his decision denying plaintiffs' motion for judgment NOV or new trial, however, Judge Rubin held that the "substantial factor" test was not recognized in Ohio and refused to apply it under *Erie*. Instead, Judge Rubin instructed the jury in the following language:

> The question you must answer is whether the plaintiffs established by a preponderance of the evidence that the ingestion of Bendectin at ther-

apeutic doses during the period of fetal organogenesis is a proximate cause of birth defects?

The term "proximate cause" is defined as that which in a natural and continuous sequence produces an injury which would not have otherwise occurred.

This does not mean that the law recognizes only one proximate cause of an injury. Thee [sic] may be more than one proximate cause. There may be other factors that operate at the same time, either independently or together, to cause an injury. In such a case, each factor may be a proximate cause.

In order to conclude that Bendectin in therapeutic doses caused a specific category of birth defects, it is not necessary for you to find that all women who ingested Bendectin delivered children with birth defects.

The ingestion of Bendectin by a pregnant women [sic] in therapeutic doses and the subsequent delivery of a child with a specific birth defect standing alone is not evidence that Bendectin caused that defect.

At all times in your deliberations on causation, you must assume that Bendectin was ingested only in doses prescribed by physicians.

In re Richardson-Merrell, Inc. Bendectin Products, 624 F. Supp. 1212, 1263 app. D (S.D. Ohio 1985) (footnotes omitted).

In arguing that Judge Rubin's instructions were erroneous and that the substantial factor test should have been applied to the causation issue, plaintiffs cite various cases which they assert support the use of the test by Ohio courts, such as *Cascone v. Herb Kay Co.*, 6 Ohio St. 3d

155, 451 N.E.2d 815 (1983). However, *Cascone* does not address the "but for" versus "substantial contributing factor" issue, but the quite different question whether an initial actor should be held liable for injuries caused by an intervening or superseding actor. The court there held that the initial actor could still be held liable if his conduct remained a substantial contributing factor to the injury. In this context, that is all "substantial contributing legal cause" refers to. *Thropp v. Bache Halsey Stuart Shields, Inc.*, 650 F.2d 817, 821 (6th Cir. 1981). Under *Cascone*, even where there is an intervening actor, however, the first step of the proximate cause analysis is whether the original tortfeasor's negligence was an actual cause or a "cause in fact" of the injury. *Id.* at 821. Plaintiffs also cite *Utzinger v. United States*, 432 F.2d 485 (6th Cir. 1970), but again that case states the rule for an intervening agent. *Cf. Hupp v. United States*, 563 F.Supp. 25, 30 (S.D. Ohio 1982). To this we must add the observation that the plaintiffs never argued that Merrell Dow was an initial tortfeasor whose drug Bendectin caused birth defects because of the act of any intervening third party. The plaintiffs affirmatively alleged in their complaint and argued at trial that the drug itself was a direct cause of birth defects without the interference of any third party. Insofar as we can ascertain, the district judge's denial of plaintiffs' proposed instruction would have been proper under the law of any state.

Plaintiffs also point to the substantial factor theory in section 432(2) of the *Restatement (Second) of Torts*, which holds that when "two forces are actively operating, one because of the actor's negligence, the other not because of any misconduct on his part, and each of itself as sufficient to bring about harm to another, the actor's negligence may be found to be a substantial factor in bringing it about." Prosser and Keeton describe the substantial factor test as applied to two actors: "When the conduct of two or more actors is so related to an event that their

combined conduct, viewed as a whole, is a but-for cause of the event, and application of the but-for rule to them individually would absolve all of them, the conduct of each is a cause in fact of the event." W. Prosser & R. Keeton, *The Law of Torts*, § 41 at 268 (5th ed. 1984) (footnotes omitted). A review of the Restatement's own comment to section 432(2) indicates that it has no application here, however. The third illustration of that section's comment concerns two fires negligently set by the separate acts of two railroads. The two fires coalesced before reaching and subsequently setting fire to a third party's property. The normal spread of either fire would have been sufficient to burn the property, and the third party barely escaped from his house. Although in that situation the plaintiff would not need to prove "but for" causation, because he could not definitely say which of the railroads had caused the fire that damaged his house, he would have to prove that both fires could have caused the damage. In fact, the requirement under the substantial factor test of section 432(2) that plaintiff first prove that the conduct of each defendant, acting alone, was sufficient to be a possible proximate cause of the injury was set forth clearly in an Ohio case cited by plaintiffs themselves. *Minnich v. Ashland Oil Co.*, 15 Ohio St. 3d 396, 398, 473 N.E.2d 1199, 1201 (1984) ("no determination has been made as to whether either defendant committed a tortious act, or whether either defendant's act was the proximate cause of appellant's injuries. These issues must be decided by a trier of fact in order to apply the Restatement rule [433B].").

Here, plaintiffs' witness, Dr. Swan, testified that in some cases, a woman might have taken Bendectin while exposed to another agent that independently causes birth defects. Although his other agent might have been present, she testified that would not mean that the contribution of Bendectin to that birth defect would have been any less. She also testified that Bendectin might act synergistically with other drugs to produce birth defects. However, section

432(2) has no relevance to the case unless the plaintiffs can show that Bendectin by itself caused birth defects, which the jury verdict indicates they did not do. Had it been established that Bendectin could bring about the harm individually and had there been cases in which Bendectin had been administered while other independent causes of birth defects were operating, then section 432(2) could apply.[14]

We conclude therefore that even if the cited Ohio cases were applied to the present case, plaintiffs would still have to prove "but for" causation rather than some weaker "substantial factor" standard.[15] The substantial factor standard applies only to initial negligent actors in determining their liability in the face of action by a subsequent actor, or in determining causation between simultaneous actors, both of whose acts could have been "but for" causes of plaintiffs' injuries. For the same reasons that the plaintiffs' complaint would not have justified this instruction under the law of Ohio, it also would not have justified this instruction under the law of any other state, and we have been led to no other persuasive authority to the contrary.

Plaintiffs also raise the argument that if causation had been tried simultaneously with their claims for breach of warranty and failure to warn, they would have had to prove merely that Bendectin increased the risk of birth defects, and not that it was a "but for" cause of them.

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[14] While we agree with the trial judge that Dr. Swan's testimony would not support application of section 432(2), it was nevertheless consistent with the court's instruction as given. It is important to observe that the jury, if it credited Dr. Swan's testimony, would plainly have understood that it could return a verdict for the plaintiffs where Bendectin was one of the proximate causes of the defects.

[15] Ohio law also rejects the related, but somewhat distinct "increased the risk" standard in these circumstances. *Cooper v. Sisters of Charity of Cincinnati, Inc.*, 27 Ohio St. 2d 242, 272 N.E.2d 97 (1971).

They cite *Tinnerholm v. Parke Davis & Co.*, 285 F.Supp. 432 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969), in support of this position. However, *Tinnerholm* is distinguishable. There, a child received a vaccine which contained four antigens, one of which was whooping cough. He subsequently suffered a degenerative disease. At a bench trial the judge found with reasonable medical certainty that the whooping cough vaccine was a cause in fact of this degenerative disease. But to find liability under the breach of warranty, it was not sufficient that the degenerative disease could be caused by the vaccine. Rather, an implied warranty breach could occur only because by manufacturing the vaccine as it did, defendant increased the chances of contracting the disease. In short, the increased risk standard came into play only after it had been determined that the vaccine could have caused the disease. Similarly, plaintiffs here could not prevail on a breach of warranty claim absent proof that Bendectin could in fact have caused their birth defects. Even if defendant failed to warn potential users that Bendectin caused birth defects, such failure to warn would be inconsequential if Bendectin could not have in fact caused birth defects:

> An act or an omission is not regarded as a cause of an event if the particular event would have occurred without it. . . . The failure to install a proper fire escape on a hotel is no cause of the death of a man suffocated in bed by smoke. The omission of crossing signals by an approaching train is of no significance when an automobile driver runs into the sixty-eighth car.

W. Prosser & R. Keeton, *supra*, § 41 at 265 (footnotes omitted). Trifurcation did not deny plaintiffs the right to have the jury consider the increased the risk standard, because that standard could have applied only had the jury affirmatively answered the question that the district court posed.

At oral argument on appeal, counsel raised yet another argument: that the trifurcation order prevented the plaintiffs from showing alternate causation. Under alternate causation, the burden would have shifted to the defendant to prove that its negligence was not a proximate cause of the birth defects. It this argument applies, the district judge would have been bound to instruct the jury that defendant had the burden of proof, since a federal court in a diversity case must apply the state court's burden of proof rules. *Palmer v. Hoffman*, 318 U.S. 109, 117 (1943). According to the plaintiffs' complaints, however, not only would plaintiffs not have been entitled to an alternate liability instruction with the shifted burden of proof in a trifurcated trial; they would not have been entitled to such an instruction even at a unitary trial. The doctrine of alternate liability simply does not apply to the facts alleged here. Cases that apply this doctrine, such as *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 163 Cal. Rptr. 132 (1980), and *Summers v. Tice*, 33 Cal. 2d 80, 199 P.2d 1 (1948), do so only when two or more defendants have been at fault, and one and only one caused the injury. Rather than dismissing for plaintiff's inability to show causation by a preponderance of evidence against any individual plaintiff, courts in this situation shift the burden of proof to the defendant to prove that he was not the negligent actor that caused the injury. This is codified in section 433B(3) of the Restatement:

> Where the conduct of two or more actors is tortious, and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm.

As the Restatement's comments to this subsection show, see for example comment (g), the rule is not applicable unless more than one defendant has been negligent. Here, however, the plaintiffs have sued only one defendant, Mer-

rell Dow. That is the only actor whose conduct was alleged to have been negligent. Therefore, the doctrine of alternate liability, even if it has been adopted in states such as Texas, as Wood's attorney contends, does not apply to the one-defendant case.[16]

Plaintiffs raise an additional argument for shifting the burden of proof to defendant regarding proximate cause. They claim that proof of a violation of the FDCA would give rise to negligence per se under *Toole v. Richardson-Merrell*, 251 Cal.App.2d 689, 60 Cal. Rptr. 398 (1967), and shift the burden to defendant to prove that Bendectin did not cause their injuries. Without trifurcation, they allege that some plaintiffs could have demonstrated negligence per se which would have enabled them to rely on a rebuttable presumption of causation based upon the violation of a statute designed to protect their safety. A cited example in support of this negligence per se argument is *Haft v. Lone Palm Hotel*, 3 Cal. 3d 756, 91 Cal. Rptr. 745, 478 P.2d 465 (1970), in which a father and son drowned in a motel swimming pool, cause unknown. Contrary to the requirements of a California statute, the motel owner had failed either to place a lifeguard on duty at the pool, or post a sign indicating that no lifeguard was on duty. The court allowed plaintiffs to sustain their initial burden of proof on the issue of causation by proving that the violation of the statutory lifeguard requirement had occurred. Then, the burden shifted to the defendant to show that its violation did not proximately cause the death. Since defendant had been negligent by violating the statute, and since the failure to provide a lifeguard greatly increased

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[16] Alternative liability also does not apply under the law of Ohio. For a plaintiff to shift the burden, he must prove that two or more defendants committed tortious acts, and that he was proximately injured as a result of the wrongdoing of one of the defendants. "This doctrine does not apply in cases where there is no proof that the conduct of more than one defendant has been tortious." *Minnich*, 473 N.E.2d at 1200.

the chances that the drownings would occur, and since the facts suggested that a competent lifeguard would have prevented the deaths, the plaintiffs according to the court, had done all that they could to prove the requisite causal connection between the negligence and the accidents. When there exists a substantial probability that a defendant's negligence caused an accident, and "when the defendant's negligence makes it impossible, as a practical matter, for plaintiff to prove 'proximate causation' conclusively, it is more appropriate to hold the defendant liable than to deny an innocent plaintiff recovery, unless the defendant can prove that his negligence was *not* a cause of the injury." *Id.*, 478 P.2d at 476 n.19.

Once again, the negligence per se argument is inapplicable to the facts of this case. The case law and legal commentary on application of the negligence per se standard in similar cases reveal that to shift the burden of proof to defendants plaintiffs must not only prove that defendant violated a statute, but also must prove that plaintiff's harm fell within the risk proscribed by the statute, or that there is a substantial probability (not necessarily more probable than not, but at least reasonably conceivable) that the violation and injuries are causally related.[17] In the present

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[17] *See e.g.*, Wright, *Causation in Tort Law*, 73 Cal. L. Rev. 1735, 1772-74 (1985). In *Stanton by Brooks v. Astra Pharmaceutical Products, Inc.*, 718 F.2d 553 (3d Cir. 1983), the court applied the negligence per se standard specially to a claim of violation of the FDCA. Although in that case the court permitted plaintiffs to rely on negligence per se for defendant's violation of the FDCA and then shifted the burden of proof to defendant, it was already resolved that the cardiac arrest that plaintiff suffered was in fact caused by the drug which defendant manufactured. The question was whether defendant was liable for plaintiff's injury for failing to provide the FDA with information on the drug after the agency had approved it. In this case, even if the doctors would have considered Merrell Dow's wrongful withholding of information from the FDA to be sufficient to stop them from prescribing Bendectin, the fact that they continued to do so despite the statutory violation would be irrelevant if Bendectin does not in fact cause birth

case we find that the plaintiffs' proof of causation between certain types of birth defects and defendant's misrepresentations and/or omissions in conducting research and labelling Bendectin is beyond the realm of common experience,[18] and thus plaintiffs would have been unable to shift the burden under the negligence per se standard even if violation of the FDCA was proved. While it is theoretically possible to envision a case where fraudulent research and mislabelling of a drug could, within the realm of common experience, be seen to cause serious injuries to purchasers following consumption, plaintiffs here have simply failed to present sufficient evidence to indicate substantial probability of a causal link between ingestion of the mislabelled drug and plaintiffs' injuries.

An additional issue that arises in considering the negligence per se argument, but which we do not address here, concerns whether Congress intended the FDCA to be used as a behavioral standard in such cases. It is clear that whether a state chooses to recognize violations of its own statutes as negligence per se is purely a question of state law. Therefore, states like Ohio are perfectly free to apply the negligence per se doctrine to violations of its own pure food and drug law, Ohio Revised Code sections 3715.52 and 3715.64. *Taugher v. Ling*, 127 Ohio St. 142, 187 N.E. 19 (1933); *Portage Markets Co. v. George*, 111 Ohio St. 775, 146 N.E. 283 (1924); *Schell v. Du Bois*, 113 N.E. 664 (1916). However, the determination that a violation of a federal statute such as the FDCA will create

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defects. The Fourth Circuit has also allowed negligence per se upon proof of a violation of the FDCA, even though it admitted that there was no express private civil remedy. *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455, 460-61 (4th Cir. 1960).

[18] At trial, the proof adduced by plaintiffs to prove causation consisted of highly technical scientific studies, including toxicity studies on laboratory animals, chemical studies of the biochemical properties of Bendectin, and epidemiological studies or case histories of persons exposed to the drug.

state tort liability is not a matter solely of state law. A state's ability to use a federal statute violation as a basis for state tort liability and negligence per se depends on the intent of Congress, and not merely on the intent of the state. *See* W. Prosser and R. Keeton, *supra*, § 36 at 220-21. Thus, the congressional decision not to provide a private cause of action under the FDCA becomes quite important in considering the propriety of a state negligence per se action for violation of the FDCA. "It may be that a decision by Congress not to create a private remedy is intended to preclude all private enforcement. If that is so, then a state cause of action that makes relief available to private individuals for violations of the FDCA is pre-empted." *Merrell Dow v. Thompson*, 106 S. Ct. at 3245 (Brennan, J., dissenting). The majority in that case also recognized that preemption might be a potential problem. *Id.* at 3236-37 (majority opinion). We recognize that a mere congressional intent to preclude a private right of action at the federal level for violations of the FDCA would not necessarily indicate that Congress intended to preclude a state remedy under a theory of negligence per se. We only observe that preemption could be yet another obstacle to plaintiffs' reliance on a theory of negligence per se.

Finally, plaintiffs argue that the proximate cause standard itself was wrong, even if trifurcation of the issue was acceptable. It is alleged that under section 433B of the Restatement plaintiffs need not prove conclusively that Bendectin was "but for" cause of their injuries. Comment (b) to that section notes that the plaintiff is not required to prove his case beyond a reasonable doubt and that, therefore, he need not eliminate all possibility that the defendant's conduct did not cause his injury. He need only introduce sufficient evidence for a reasonable person to decide that it was more likely that the injury was caused by the defendant than that it was not. If, as matter of ordinary experience, a particular act would be expected to

produce a particular result, and that result has in fact occurred, the jury might be justified to conclude that the causal connection exists. This would be so even though the plaintiff has not proven that but for the defendant's act, his particular injury would not have occurred.

Section 433B has its roots in Judge Learned Hand's opinion in *Zinnel v. United States Shipping Board Emergency Fleet Corp.*, 10 F.2d 47, 49 (2d Cir. 1925). That case involved the death by drowning of a seaman. The owner of the ship did not provide ropes in the ship that might have been used to rescue drowning sailors. The circumstances of death were such that the plaintiff could not prove that had the defendant provided the rope the decedent would have survived. Although the plaintiff could not prove "but for" causation of the injury by the defendant's negligence, Judge Hand allowed recovery because the jury could rely on its common experience that had the rope been provided the result would have been more likely than not that the sailor would not have drowned.

In comment b of section 433B of the Restatement, three illustrations demonstrate the circumstances under which an alternate jury instruction for causation may be employed. In each of these examples, the element of common experience is vital to the finding of causation. In the present case, however, the linkage between ingestion of the drug and the birth defects is simply not supplied by common experience, and thus the implicit prerequisite for an alternate jury instruction under section 433B is missing. Furthermore, our review of the case law reveals no court that has extended comment b of section 433B to allow for an alternate jury instruction in toxic tort cases.

B. TRIFURCATION AS A POTENTIAL SOURCE OF UNFAIR PREJUDICE

Plaintiffs also argue that the decision to trifurcate the trial was an abuse of discretion because the ruling unfairly

prejudiced presentation of their case in a variety of ways. First, one of the plaintiffs' attorneys alleges that the decision to trifurcate was rendered after discovery had been completed and allowed him only two months to reorganize depositions and videotape testimony for a trial limited to the issue of proximate causation. Factually, this claim is inaccurate. Plaintiffs actually had ten months to revise the videotape depositions. The trail was postponed from June 1984, two months after the decision to trifurcate, to February 1985 because of the settlement negotiations. Plaintiffs argue that not all of this additional eight months could be used to reorganize the materials for trial, due to the settlement negotiations. While settlement discussions often dull the edge of advocacy, they do not provide a legal excuse for failure to continue preparations for trial. Had counsel for plaintiffs genuinely feared prejudice, they could have made a request to reopen discovery. While they claim on appeal that they did make such a request, the record does not support it. The plaintiffs further argue on appeal that the testimony of their witness, Theirsch, became unintelligible as a result of the removal of non-causation liability evidence. Our examination of Theirsch's testimony, including the specific page references cited to us, satisfies us that his testimony was intelligible despite its editing to eliminate references to liability. Plaintiffs had ample time in which to rearrange their proof, and they never requested more. The care and legal skill demonstrated in their advocacy leads us to conclude that they perceived no prejudice in fact from the amount of time available to them to reform their strategy. Neither do we.

The plaintiffs also challenge the trifurcation order because even had they won this stage of the trial, the court gave no assurance that the same jury that heard the evidence on causation, and rendered them a favorable verdict, would decide the question of liability. Plaintiffs' attorney Chesley specifically repeated this assertion at oral argument. The facts are otherwise. In Mr. Chesley's presence,

the district judge indicated "that if the plaintiffs prevailed . . . the same jury [would] be used for the next phase of the trial." Judge Rubin did, however, offer to impanel a new jury if both sides so requested. No objection was raised to either comment, and, in fact Mr. Chesley explicitly indicated that it would "not [be] impossible to seat a new jury." Even had such a procedure been contemplated, and we emphasize that it was not, the party challenging such a procedure was willing to accept it below. In his argument on behalf of plaintiffs-on appeal, Professor Arthur Miller acknowledged that there is no constitutional prohibition against trying these issues before different juries. *Cf.* 9C, Wright, A. Miller & F. Elliott, *supra*, § 2391 at 302.

Plaintiffs' next challenge the decision to trifurcate on the proximate causation question because the issue trifurcated was the one which a lay jury would be least qualified to understand, evaluate, and decide. The district judge offered to try the case before a blue ribbon jury, but the plaintiffs rejected the idea. This was, of course, their right. In any event we conclude that if the issues were indeed difficult, their resolution was not rendered more difficult due to trifurcation. If anything, the narrowing of the range of inquiry through trifurcation substantially improved the manageability of the presentation of proofs by both sides and enhanced the jury's ability to comprehend the causation issue.

Plaintiffs' primary argument against trifurcation as unfairly prejudicial is that trying the question alone prejudiced plaintiffs by creating a sterile trial atmosphere. In *Beverly Hills,* we addressed similar concerns that trifurcation could possibly prevent the plaintiffs from exercising their right to present to the jury the full atmosphere of their cause of action, including the reality of injury:

> A strong argument can, it is true, be made against the bifurcation of a trial limited to the

> issue of causation. There is a danger that bifurcation may deprive plaintiffs of their legitimate right to place before the jury the circumstances and atmosphere of the entire cause of action which they have brought into the court, replacing it with a sterile or laboratory atmosphere in which causation is parted from the reality of injury. In a litigation of lesser complexity, such considerations might well have prompted the trial judge to reject such a procedure. Here, however, it is only necessary for us to observe that the occurrence of the fire itself, a major disaster in Kentucky history by all standards, was generally known to the jurors from the outset. Further, the proofs themselves, although limited, were nonetheless fully adequate to apprise the jury of the general circumstances of the tragedy and the environment in which the fire arose. As a result, we hold that the trial judge did not abuse his discretion in severing the issue of causation here.

Beverly Hills, 695 F.2d at 217. Judge Rubin considered this language when he denied the plaintiffs' motion for a new trial. On appeal plaintiffs also rely heavily on the same langauge.[19] Sterility is not necessarily the inevitable consequence in a trifurcated trial merely because the jury may not hear the full evidence of defendant's alleged wrongdoing. It more properly refers to the potential danger that the jury may decide the causation question without appreciating the scope of the injury that defendant supposedly caused and without the realization that their duties involve the resolution of an important, lively and human controversy. It is with respect to this latter concern

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[19] Plaintiffs maintain that the exclusion of all visibly deformed plaintiffs from the courtroom, as well as all children under ten, whether or not visibly deformed, also contributed to sterile or laboratory conditions. We address this argument in part VI, *infra*.

that the plaintiffs urge that they were unfairly prejudiced by the trifurcation. The record reveals that the district judge consciously worked to avoid the potential for unfair prejudice. For example, he instructed the jury:

> Let me suggest to you that what you are about to do may be one of the most important things you will ever do in your entire entire [sic] life. This is a significant case. It involves a lot of people. It involves not only the plaintiffs who are individuals, it involves people, scientists, people who have done experiments, people who are employees of the defendant company. The totality of this case involves people and while you will hear technical evidence, I do point out to you that at all times, you should keep in mind that on both sides, there are people involved.

The court was not alone in efforts to avoid the dangers of sterility. In his final argument, plaintiffs' attorney Eaton told the jury that the trial was not an academic exercise, and that the case involved many real people who sought justice, and who would, as children, be affected by the jury's verdict well into the next century.

Finally, plaintiffs argue that Judge Rubin failed to consider the caveats of Rule 42(b) in his trifurcation decision, and instead justified trifurcation only upon unsubstantiated claims of judicial efficiency, thus unduly prejudicing plaintiffs' case without good reason. We believe, however, that the district judge carefully made the necessary inquiry. In his final order the trial judge noted that Bendectin litigation could "substantially immobilize[e] the entire Federal Judiciary. There have been only four cases involving Bendectin which have been individually tried. They required an average of 38 trial days." *In re Bendectin*, 624 F.Supp. at 1221. Judge Rubin calculated that if all 1100 cases were tried at that average length on an individual basis, they would be able to keep 182 judges oc-

cupied for one year. *Id.* at n.6. Contrary to the plaintiffs' claims that Judge Rubin never considered the language of Rule 42(b), he did correctly require plaintiffs to prove that the defendant's drug caused their injury, and would not allow plaintiffs to buttress a weak causation case with a strong negligence case. Thus, in line with the language of Rule 42(b), the trial judge considered the causation question to be a separate issue.

In reviewing the district court's decision to trifurcate we further note Rule 42 which "giv[es] the court virtually unlimited freedom to try the issues in whatever way trial convenience requires." C Wright, A Miller & F. Elliott, *supra*, § 2387 at 278. Thus, a court may try an issue separately if "in the exercise of reasonable discretion [it] thinks that course would save trial time or effort or make the trial of other issues unnecessary." *Richmond v. Weiner*, 353 F.2d 41, 44 (9th Cir. 1965). In this case, the district judge considered the time savings in trying this case in this fashion, and surmised that if the plaintiffs won on this issue, another eight weeks of trial would be necessary to resolve the other questions.

Many courts have in fact permitted separate issue trials when the issue first tried would be dispositive of the litigation. The courts do so because the efficiency of the trial proceedings is greatly enhanced when a small part of the case can be tried separately and resolve the case completely. For example, in *Yung v. Raymark*, 789 F.2d at 401, we recently approved the separate trial of the issue of statute of limitations because if that issue were resolved to bar recovery, the court would be spared the necessity of trying liability and damages. "Whether resolution of a single issue would likely dispose of an entire claim is extremely relevant in determining the usefulness of a separate trial on the issue. . . . This procedure should be encouraged because court time and litigation expenses are minimized." *Id.* (citation omitted). The defendant relies heavily on language like this. As the defense correctly

observed: "[T]he plaintiffs can never win a case if they can't prove the drug caused the problem. That is the central issue in this case." And later, "[a]ll claims depended upon the answer to a single question. Does Bendectin, taken in therapeutic doses cause birth defects?" Plainly, Judge Rubin had a massive case management problem to resolve, and chose to do so by trying the case on a separate issue that would be dispositive.

C. CLAIMS OF PREJUDICE RESULTING FROM EXCLUSION OF EVIDENCE BEARING ON CAUSATION

While we have held that proximate causation is a separate legal question, that trifurcation did not unfairly prejudice more general aspects of plaintiffs' case, and that trifurcation furthered economy in this case, we must still consider whether trifurcation unduly prejudiced plaintiffs by restricting the evidence they could bring forth in proving the proximate causation issue.

First, plaintiffs argue that this format prejudiced them because it precluded them from introducing evidence about the individual circumstances of different plaintiffs concerning their ingestion of the drug. Although the record on this point is not completely free of doubt, the court did not exclude all evidence of the effect of the drug on individual plaintiffs. The plaintiffs stated that they intended to have Dr. Done testify about individual cases, and it is significant in our view that the court denied the defendant's motion to preclude such testimony. The plaintiffs never offered such testimony, and they were not precluded from doing so. Thus, there was no evidence offered that individual circumstances in ingesting Bendectin had any causal relationship to birth defects, even though the district judge allowed plaintiffs to introduce evidence of individual differences. Plaintiffs' argument, asserted repeatedly at oral argument and in their briefs, that the district judge precluded factual testimony is also not supported by the record. Factual testimony was permitted on

rebuttal, and plaintiffs chose to subpoena only one factual witness. We can only conclude that their decision was tactical. We perceive no reversible error in this regard.

Plaintiffs also assert on appeal that they were unable to argue that there was a genetic susceptibility to Bendectin that varied among individuals, and that the jury should have been so instructed. The plaintiffs were not precluded from arguing that there was an individual susceptibility to Bendectin, but all their witnesses testified only that there were individual genetic susceptibilities to drugs in general. No one testified that there was such a susceptibility to Bendectin. Judge Rubin therefore correctly advised counsel that if the plaintiffs argued to the jury that there was such an individual susceptibility to Bendectin, he would have to instruct the jury that there was no evidence to that effect.

Probably the plaintiffs' most serious charge is that the trifurcation format prevented them from challenging the validity of various studies that the defendant relied on in support of its position that Bendectin did not cause birth defects. For example, at oral argument plaintiffs' counsel represented that while plaintiffs could attack part of the Bunde-Bowles study defendant had used to justify the safety of Bendectin, most of the study could not be criticized because of limitations placed upon counsel by the court. Also, co-counsel alleged at oral argument that when the defendants relied on a particular study, the plaintiffs tried to cross-examine these studies' methodology and biases, but the district judge prevented this line of inquiry because of the trial's limitation to causation. These assertions would be potentially serious except that they are not supported by the record.

For example, the plaintiffs complain that they could not show criminal conduct and fraud in the preparation of the Bunde-Bowles study. It is true that the district judge would not allow testimony going to the fraudulent preparation

of this study, but he did not preclude proof affecting the accuracy of test results indicating that Bendectin did not cause birth defects. Although a fraudulent motive might be more dispositive of the value of a study, it is also in most cases a prejudicial and inaccurate gauge of how incomplete a scientific study actually is. Instead the most effective way to discredit these studies is through a critique of their technical flaws, as was done here.

Similarly, plaintiffs challenge the inadmissibility of a portion of a letter prepared by one of the testers in Merrell's 1970's study, the Smithells study. Specifically, the plaintiffs wanted to introduce a letter written by Smithells to Merrell Dow that mentioned his hope that publication of his study would save the defendant large sums of money defending California litigation. The district judge refused to admit this letter. He said that this went to classical bias of the person conducting the study, and not scientific bias that would go to whether the study was actually accurate. As long as the methodology was correct, the fact that somebody might have intended to use the results in a particular way would be of no consequence. Additionally, the trial judge held that any reference to this sort of bias could create the potential for undue prejudice to defendant. We see this narrow ruling as merely a careful balancing of the factors of relevancy and prejudice under Fed. R. Evid. 403.

Moreover, while plaintiffs were unable to introduce the letter from Smithells regarding assistance to the defendant in its California litigation, they remained free to attack any methodological flaws of that study, and they did. Dr. Swan testified that the Smithells study had no internal control group, and did "not contribute meaningfully to the body of literature." She further testified, despite the inadmissibility of the letter, that the Smithells letter itself would lead her to remove the study on the grounds of bias. Plaintiffs' attorney Bleakley also cross-examined defendant's witness Dr. Hall regarding the Smithells study.

Plaintiffs were similarly afforded broad latitude in their efforts to prove that various other studies by the defendant were false. Much of plaintiffs' efforts in this regard were focussed on discrediting the Bunde-Bowles study. For example, Dr. Done testified that Bunde-Bowles was "a poorly designed study, and one really destined not to be likely to provide very useful information." He indicated that the numbers in the Bunde-Bowles samples were too small, that the controls were not matched for age or for other drugs, and that the study suffered from poor record keeping. Dr. Done also testified that the Bunde-Bowles data were suspect because the test found fewer malformations in the treated group which might suggest a protective effect for the drug, while three was no reason that a pharmacist would expect this to happen. He further testified that patients who were supposed to have used Bendectin, *i.e.* the experimental group, may not have in fact ingested it because there was nothing to record that they had ever been administered the drug. He testified that from looking at the original patient records, he could not be sure whether the patients alleged to have taken Bendectin actually did. Moreover, some patients were included as both Bendectin takers and controls. "[T]here were enough of them to make the entire contribution from that particular practice to this study to have [sic] to be very seriously questioned." Dr. Done stated that if someone were to eliminate what he thought were the suspect data in Bunde-Bowles, instead of producing a 50% greater relative risk for birth defects among the control group than among Bendectin users, there would be rather a 30% higher risk for those who had taken Bendectin. Dr. Done further testified that the Bunde-Bowles study may not have used a normal population group and that this might have been particularly a problem if the control group was not similar in its preselection criteria. He highlighted the fact that many of the survey participants had come from one doctor's practice. Finally, he said "[t]hat from the scientific standpoint, the

[Bunde-Bowles] study is totally worthless." Dr. Swan also criticized the study. She said that the study was incapable of detecting a relative risk for limb reductions that was smaller than sixfold. She also criticized the sample size in the Bunde-Bowles study. Defendant, of course, vigorously contested these assertions.

Judge Rubin specifically told the plaintiffs that, "[i]f a witness has relied upon a study and it is demonstrably inaccurate, false, you are entitled to develop that in cross-examination." Thus the plaintiffs not only attacked Bunde-Bowles in direct examination of their own witnesses, but they also attacked Bunde-Bowles when cross-examining the defendant's witnesses. For example, plaintiffs' attorney Skinner cross-examined defendant's witness Dr. McClain about the Bunde article. The plaintiffs also criticized Bunde-Bowles in their closing arguments. For example, one of plaintiffs' attorneys, Mr. Eaton, admitted that plaintiffs had been able to criticize the Bunde-Bowles study:

> THE COURT: The Bunde-Bowles study you have done in great detail to show its unreliability. This isn't brand new.
>
> MR. EATON: We haven't even started to show how unreliable the study is, because we haven't been allowed to.
>
> THE COURT: I don't think that's true. Look, Mr. Eaton, be very careful what you are saying, because the Bunde-Bowles study has been referred to in this case, and I am unaware of any portions of it that you weren't allowed to use. I think there's an inference in the record here that I don't appreciate.
>
> MR. EATON: Please, forgive me, Your Honor, I certainly—the only thing I was referring to yesterday, we—this is all I was taxing about—that weren't allowed to introduce the actual evidence,

> and I don't want you to think for a moment, Your Honor, that there was anything inferred [sic] beyond that.

In the context of the record, Mr. Eaton was only referring to the Court's prior ruling disallowing introduction of the original patients' records used in the Bunde-Bowles study due to a lack of foundation with the expert witness. Nonetheless, on appeal, the plaintiffs seek to create the same impression that the district judge so objected to below. It is quite clear that the plaintiffs were able to thoroughly attack the methodology and technical inadequacies of the Bunde-Bowles study.

There were also criticisms of various other studies defendant had relied on to show that Bendectin did not cause birth defects. Dr. Done criticized the animal studies, as "not sufficient enough or adequate enough for me to accept them as indicating the lack of showing of teratogenicity." He also criticized the Research Triangle study, the McBride study, and the Hendricks study. Dr. Swan commented that the Correy and Newman study lacked an internal control group. She noted that the Milkovich and Vandenburg study was unable to detect a minimum risk smaller than twelvefold. She made a similar criticism of the Heinonen-Shapiro publication, and said that most of this study was inconclusive. Dr. Melnick criticized the methodology of the Staples study. While defendant objected, on the ground that "what they are really doing is attempting to show negligence in regard to the way that this test was done," the district judge overruled this objection. Dr. Melnick also criticized animal studies that the defendant conducted in 1966 and 1975. The plaintiffs cross-examined defendant's witness Dr. Holmes about the study that he undertook with Dr. Jick. On rebuttal, plaintiffs' factual witness Petrow criticized a 1963 rabbit study, the Staples study, and 1966, 1967, and 1975 animal studies. And, in his closing argument, Eaton criticized various studies of the defendant, including Staples, and the 1966 an-

imal studies. In sum, plaintiffs would have us hold that their failure to persuade the fury resulted from the district judge's improper preclusion of evidence. It did not. The issue of causation was thoroughly and skillfully presented by both sides.

D. CONCLUSION

To summarize, the three considerations we apply in reviewing a decision to try an issue separately are (1) whether the issue was indeed a separate issue, (2) whether it could be tried separately without injustice or prejudice, and (3) whether the separate trial would be conducive to judicial economy, especially if a decision regarding that question would be dispositive of the case and would obviate the necessity of trying any other issues. We hold that since the initial trial on the proximate causation issue was a separate issue, promoted efficiency, and did not unduly prejudice plaintiffs, trifurcating this case on the separate issue of proximate causation was proper. We need not decide whether this was the best or even the only good method of trying this case. We need only determine whether, under all of the circumstances before him, the trial judge's decision to trifurcate was an abuse of discretion.

While Ohio tort law does govern all suits originally filed in Ohio state courts or in federal courts located in Ohio, under our previous conflict of laws analysis, it is not clear that Ohio tort law would apply to those claims filed initially in other states or federal courts outside of Ohio, which were subsequently transferred to Ohio. Based on the cases cited by plaintiffs and a thorough search of the literature on causation however, we are not persuaded that the law in any American jurisdiction would preclude separation of the issues of causation and culpability in such complex cases as the present one. Therefore, we conclude that the district judge did not abuse his discretion in determining

to try causation as a separate issue as to all plaintiffs over which that court had jurisdiction.

V. GENERAL EVIDENTIARY QUESTIONS

Although the district judge's decision to trifurcate the case on the issue of causation was proper, plaintiffs raise specific evidentiary objections to his rulings regarding the admissibility of certain evidence, or the preclusion of their ability to make certain references at trial. The range of discretion contemplated by Rule 42(b) makes such issues inevitable where less than the entire lawsuit is tried.

One evidentiary challenge that the plaintiffs raise concerns them defendant's ability to argue that it has complied with all FDA statutory and regulatory requirements, while the plaintiffs were precluded from introducing evidence tending to show that the defendant deceived the FDA regarding the validity of their test results. Despite plaintiffs' allegations, however, FDA approval of Bendectin was not allowed to be admitted. The trial judge indicated this was to benefit plaintiffs, because they did not have to make an additional argument that the tests that the FDA relied on were inadequate. Nonetheless, defense attorney Woodside did say in his opening argument, "Now, it's important to understand that Merrell followed the rules completely as it pertains to the submission of the MDA and submission of data to the Food and Drug Administration." In fact, that issue had already been injected by plaintiffs' attorney Eaton when he mentioned that the FDA had not effectively monitored the testing of this drug. Eaton also asserted that the FDA would not have approved it had they known the facts of the testing. However, at trial, Judge Rubin scrupulously indicated that he would not allow either side to address the issue of FDA approval. For example, when defendant's witness Newberne, unprompted by the defense attorney, referred to the FDA a few times, the district judge twice told the defendant's attorney, "[t]ell your witness not to refer to

the Food and Drug Administration." The plaintiffs also challenged introduction of testimony by defense witness Goddard, a former FDA commissioner, because this would allegedly imply that he and the FDA had approved the safety of the drug. The judge, however, drew a distinction, and said he would not allow testimony regarding FDA approval or lack of approval. He told the defense attorney to let him know if FDA compliance would come up in the testimony. However, the plaintiffs asked this witness about the FDA anyway. They introduced his appointment book as FDA commissioner, and then the judge indicated that they had opened the FDA door:

> Mr. Eaton, any reference to the FDA is potentially harmful to you and helpful to the defendant. It was in an effort to protect the plaintiffs that I have ruled that that could not be admitted, that the FDA is a collateral matter. . . .I thought I was protecting the plaintiffs against any inference that the FDA assisted Bendectin or that they can gain benefit from it. This is a witness that I recognized had some dangers, and I thought I was being very careful. But if you elect to raise the question, as you are doing, of his services with the FDA on a day-to-day basis, then the shield no longer exists, and I will take their questions on redirect on a question-by-question basis.

Thus, the district judge carefully prevented any references to FDA approval from entering the trial itself, and neither side raised the FDA until the plaintiffs did so late in the course of the trial. The record offers no support for plaintiffs' claim that a one-sided advantage was given to the defendant to argue that the FDA had approved its drug, while the plaintiffs could not argue to the jury that this approval had been procured through fraud.

The plaintiffs also challenged the district judge's prevention of references to the drug Thalidomide. This was a drug tested in the early 60's by the defendant, although it did not produce it. The drug was administered to pregnant women, and produced large numbers of birth defects, specifically fin-like structures on many babies. The public outcry from this drug led to strict amendments to the FDCA in 1962. *See* S. Rep. No. 1744, 87th Cong., 2d Sess., *reprinted in* 1962 U.S. Code Cong. & Admin. News 2884, 2905-2907 (views of Senators Estes Kefauver, John A. Carroll, Thomas J. Dodd, Philip A. Hart, and Edward V. Long). The district judge determined to exclude any reference to Thalidomide by name at trial because the potentiality for creating prejudice substantially outweighed any relevancy considerations. The plaintiffs claim that many of their experts obtained their credentials in the field of teratogenicity from dealing with Thalidomide, and the preclusion of reference to this fact harmed their case. Plaintiffs further argue that many of the tests that the defendants relied on to prove that Bendectin did not cause birth defects also failed to show that Thalidomide caused them, and thus they should have been allowed to refer to Thalidomide by name.

The objections of the plaintiffs and the trial court's response to them are set forth in detail in its published opinion denying plaintiffs' motions for judgment NOV and for new trial. *In Re Richardson-Merrell, Inc. Bendectin Products,* 624 F.Supp. 1212, 1236-1237 (S.D. Ohio 1985). The record demonstrates that the trial court administered its Fed. R. Evid. 403 ruling evenhandedly. For example, Judge Rubin instructed the jury to disregard the question and answer when defendant's counsel Woodside questioned Dr. McMahon about an analogous drug (referring to Thalidomide), even though no reference had been made to that drug. Early in the trial the judge showed some willingness to permit reference to Thalidomide by plaintiffs' attorneys who told him that an article that the defendant wanted

to introduce said that Thalidomide was not a teratogen. The judge indicated he would allow this reference, but that he would not allow Merrell Dow to be tied to Thalidomide since it had not manufactured it (it had, however, researched and tested it). The judge then learned that the article did not actually say that Thalidomide was not a teratogen, however, and he thereupon refused to allow the plaintiffs to refer to Thalidomide in that context. Moreover, Judge Rubin allowed references to the defendant's studies' inability to detect that Thalidomide was a teratogen, although he would not allow reference to Thalidomide by name. For example, Dr. Newman testified for the plaintiffs that some of the studies had failed to miss "[v]ery powerful substances, maybe the most powerful teratogen known to man." Dr. Melnick testified that one of the studies did not indicate that "the most devastating teratogen that we know" was missed by rat studies until the defects were found later in humans.

We review the judge's decision to exclude a reference to Thalidomide on Fed. R. Evid. 403 grounds under the following standard:

> "If judicial self-restraint is ever desirable, it is when a Rule 403 analysis of a trial court is reviewed by an appellate tribunal. . . . [T]he draftsmen intended that the trial judge be given a very substantial discretion in 'balancing' probative value on the one hand and 'unfair prejudice' on the other, and that he should not be reversed simply because an appellate court believes that it would have decided the matter otherwise. . . ."

United States v. Zipkin, 729 F.2d 384, 390 (6th Cir. 1984), quoting *United States v. Long,* 574 F.2d 761, 767 (3d Cir. 1978). Under this standard of review, we uphold Judge Rubin's determination that references to Thalidomide would be extremely prejudicial. We do not believe that plaintiffs were hindered by prohibition of references to Thalidomide.

The credentials of the plaintiffs' expert were presented to the jury in the same manner as the defendant's experts were.

Another objection concerns the district judge's repeated references to defendant's attorney as "Dr." Woodside. The plaintiffs argue that this gave an unfair credibility advantage to the defendants. It should be noted that Dr. Woodside has a medical degree and is indeed a doctor as well as an attorney. Thus, the judge was not calling Dr. Woodside a doctor when in fact he had a Ph.D. or no doctorate at all. We agree that a better course would have been to address Woodside in the capacity in which he was then acting, as an attorney. We note, however, that during the trial, plaintiffs' counsel Mr. Skinner elicited from Dr. McClain, one of the defendant's experts, that the latter had taught Dr. Woodside medicine. We find no legal error in either respect.

Finally, the plaintiffs challenge the fact that Judge Rubin instructed the jury that the defendant was an "honest drug company," even though the plaintiffs were not able to raise any prior fraud or criminal conduct that the defendant or its employees had committed. In fact, the district judge never instructed the jury that the defendant was an honest drug company. The actual instruction given was:

> The fact that the plaintiffs are individuals and the defendant is a corporation must not enter into or affect your verdict. This case should be considered and decided by you as an action between persons of equal standing in the community, of equal worth and holding the same or similar station in life.
>
> A corporation is entitled to the same fair trial as a private individual. The law is no respecter of persons. All persons including corporations stand equal before the law and are to be dealt with as equals in a Court of Justice.

The claim of counsel for the plaintiff that the trial judge referred to defendant as "an honest drug company" is wholly without foundation.

VI. EXCLUSION OF ALL PLAINTIFFS UNDER 10 AND ALL PLAINTIFFS OVER 10 WHO WERE VISIBLY DEFORMED.

The plaintiffs challenge on Fifth and Seventh Amendment grounds the district judge's decision to exclude from the courtroom all plaintiffs under 10, and those who were over 10 but were visibly deformed. The district judge did this upon defendant's motion, without actually having observed any of the plaintiffs. A separate room was set up for those plaintiffs who were interested in being in the courthouse. They were provided with closed circuit television of the proceedings as well as communications equipment to assist their attorneys if the situation arose in which they were willing and able to do so. There was nothing in the record that indicates that the plaintiffs in this separate room ever contacted their attorneys to assist them. The plaintiffs argue that the defendant did not show how the presence of any plaintiffs would substantially impair the jury's performance of its duties. They maintain that the plaintiffs would have been of assistance to counsel because they could have exhibited injuries that supported the testimony of the experts. Further, plaintiffs claim the jury did not even see photographs of what the injuries were. There was also no determination made that the younger plaintiffs could not comprehend the proceedings. In fact, the jury only saw plaintiffs without injuries, at least that were visible, and this hurt the credibility of the plaintiffs' case.

In response, the defendant argues that the plaintiffs do not have standing to challenge the exclusion. We disagree.[20] In any case, the defendant argues that the excluded

[20] Merrell Dow argues that the real plaintiffs in this case are the

plaintiffs who did want to attend could view the trial and could communicate with counsel and that those plaintiffs who were excluded could not educate counsel given the scope of this trial. Also, the defendant argues that the plaintiffs wanted the children to be present during the entire trial, and not for a short period of time, and that the presence of large numbers of deformed persons would unfairly prejudice and inflame the jury.

In considering both parties' arguments we are also cognizant of a very similar case decided by our court, *Helminski v. Ayerst Laboratories*, 766 F.2d 208 (6th Cir. 1985). In *Helminski*, the minor plaintiff, who suffered arrested neurological development and was autistic, was called as a witness for five minutes. The defendant objected on the ground that the jury had already been graphically told about the plaintiff's condition, and the defendant argued that the plaintiff's presence in the courtroom would prejudice the jury. We recognized there that neither the Due Process Clause of the Fifth Amendment nor the Seventh Amendment's guarantee of a jury trial granted a civil litigant the absolute right to be present during the trial of his case. We did, however, hold that "[c]onsistent with due process, a plaintiff who can comprehend the proceedings and aid counsel may not be excluded from any portion of

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parents and that therefore no plaintiff, i.e parent, has standing to raise the exclusion of the children. This argument is without merit. Plaintiffs generally must assert their own legal rights and interests and cannot base their claim to relief on legal rights or interests of third parties. *See Warth v. Seldin*, 422 U.S. 490, 499 (1975). Where, however, "as a result of the very litigation in question, the constitutional rights of one not a party would be impaired, and where he has no effective way to preserve them himself, the Court may consider those rights as before it." *United States v., Raines*, 362 U.S. 17, 22 (1960). Thus, the only way for the rights of these plaintiffs to be protected, assuming that they have been violated, is for the parents to be able to raise their children's due process rights. Additionally, "the minor is the real party in interest in a suit brought by a next friend." *Helminski v. Ayerst Laboratories*, 766 F.2d 208, 213 (6th Cir. 1985).

the proceedings absent disruptive behavior or a knowing and voluntary waiver. Thus, a plaintiff with a solely physical abnormality may not be excluded involuntarily, absent disruptive behavior, even when the abnormality is due allegedly to the defendant's wrongful conduct." *Id.* at 216-17. We noted that a hearing on the potential jury prejudice issue, in which the court observes the injured party, will best protect the litigant's right to be present, as well as the other side's right to a fair trial. At the hearing, the defendant who claims that a plaintiff's mere presence will prejudice the jury must bear the burden of persuasion on this issue. *Id.* at 217. We refused to permit a presumption that an injured party's mere presence will always deter the jury from deciding the case on the facts. *Id.* " 'The issue which the district court must resolve at the hearing is whether the party's presence would 'prevent or substantially impair' the jury from performing its duties 'in accordance with [its] instructions and [its] oath.' " *Id.* at 217 (citation omitted). The defendant must establish that the plaintiff's appearance or conduct is likely to prevent the jury from performing its duty. At the hearing, the plaintiff's ability to comprehend the proceedings or assist counsel is not the relevant inquiry. *Id.* at 218. If after the hearing, the district court determines the threshold inquiry, that a party's mere presence would be prejudicial, the court must next consider whether the party can assist counsel and understand the proceedings. If the court concludes that the party can so assist and comprehend, then the party may not be involuntarily excluded regardless of prejudicial impact *Id.* at 218. In those cases, cautionary instructions can be read that would protect the interests of the defendant. If the party can aid counsel and comprehend the proceedings, due process requires that he be present. In *Helminski,* we decided that the injured minor party was improperly excluded from the courtroom because the district court never observed him to see whether his appearance or behavior would create prejudice. How-

ever, because it was evident the minor plaintiff had been unable to comprehend the proceedings or aid counsel, we did not reverse. *Id.* at 218-19.

While we shall address later the question of retroactivity, we note initially that at the time the district judge set the rules governing the trial here, our decision in *Helminski* had not yet issued. Moreover, based on the numerosity of plaintiffs, it was evident that the facilities of the courtroom would be totally inadequate to contain all of the parties at interest, whether parents or injured children. Therefore, it was not unreasonable, in our judgment, for the trial judge to provide at least some rules for the allocation of courtroom space. It is also to his credit, as we have already noted, that he provided separate facilities from which the proceedings could be observed through closed-circuit television by those who could not for one reason or another attend at trial. When the objections to his orders of exclusion were renewed in post-trial motions, Judge Rubin correctly observed that no claim had ever been advanced that the excluded children could themselves have meaningfully assisted counsel in the presentation of the phase of the trial which was then underway and that this ruling was never tested by plaintiffs' counsel to seek an exception which they might have considered to be justified under the particular circumstances

More important, the verdict in this case was returned in March of 1985, and *Helminski* was not decided until the following June. Denial of plaintiffs' motion for judgment NOV or new trial did not occur until September 1985. Concerning retroactivity *Chevron Oil Co. v. Huson*, 404 U.S. 97, 106-07 (1971), has this to say:

> First, the decision to be applied nonretroactively must establish a new principle of law, either by overruling clear past precedent on which litigants may have relied, or by deciding an issue of first

> impression whose resolution was not clearly foreshadowed.
>
> Second, it has been stressed that "we must. . .weigh the merits and demerits in each case by looking to the prior history of the rule in question, its purpose and effect, and whether retrospective operation will further or retard its operation." Finally, we have weighed the inequity imposed by retroactive application, for "[w]here a decision of this Court could produce substantial inequitable results if applied retroactively, there is ample basis in our cases for avoiding the 'injustice or hardship' by a holding of nonretroactivity." (citations omitted).

In *Chevron* itself, the Court held that the decision whose retroactivity was at issue would not be applied retroactively because the case was one of first impression and it overruled a long line of decisions in that particular circuit. *See id.* at 107-08. In fact, the retroactivity analysis was applied to all aspects of that decision, even though the case was only in discovery at the time that the decision whose retroactivity to be analyzed was handed down. *See id.* at 99.

We noted in *Cochran v. Birkel*, 651 F.2d 1219, 1223 n.8 (6th Cir. 1981), that under *Chevron* the presumption is that a newly announced rule will apply retroactively and that the burden of persuasion is upon the party asserting prospective-only application. Applied here, the fact that a twenty-two day trial had already been concluded, and a jury verdict rendered, before the *Helminski* decision came down is certainly a factor to be considered in determining whether or not it would be equitable to apply *Helminski* retroactively. *Pitts v. Frito-Lay, Inc.*, 700 F.2d 330, 334 (6th Cir. 1983). Further, the rule announced in *Helminski*, requiring a hearing to determine prejudice and permitting a plaintiff to attend despite that prejudice if he or she

may assist or aid counsel, was not supported by any specific Sixth Circuit or Supreme Court cases. The cases relied upon were state cases from places such as New York and Florida. In short, *Helminski* was a case of first impression in this circuit, and the result was not clearly foreshadowed. Thus, we conclude that the burden of establishing the non-retroactivity of *Helminski* was met. There is no pre-*Helminski* law in this circuit that would prohibit the district court's decision.

Even if *Helminski* were to apply here, we doubt that the trial judge's decision would have been significantly different, given the proportions of the trial. Although counsel argues that individual plaintiffs could have assisted counsel by showing examples of particular birth defects, the same counsel indicated at the August 2, 1985 hearing that the one thing that the plaintiffs could have supplied had they been present would have been "the humanistic aspect of this litigation," not that they would have been able to aid or assist counsel.

Possessed of no case law in our circuit on the subject, and concerned that the presence of dozens or even hundreds of deformed plaintiffs in his courtroom might unfairly deter the jury from deciding the issue at hand in accordance with the evidence, Judge Rubin instead allowed the plaintiffs who were interested to view the trial on closed-circuit television and to assist counsel through communicative devices if they were so willing and able. This, in our view, was a reasonable way to balance the rights of the plaintiffs and the defendants in the absence of hindsight. It is true that in *Helminski* the jury, although unable to view the minor plaintiff, had received a fair amount of evidence concerning his physical condition. In this case, plaintiffs correctly observe that there was no evidence admitted as to the physical condition of individual plaintiffs. However, that was not because the judge was unwilling to let it in. At trial, attorney Chesley recognized that he

was not precluded from introducing photographs, diagrams, or skeletons.[21]

Finally, we note that *Helminski* deals not with the cause of action at issue nor with the evidence to prove it but with the important but not controlling question of trial conduct. As such, it is here believed to be subject to the harmless error provision of Fed. R. Civ. P. 61. *Helminski* will, of course, be retroactive as to any pending cases which have yet to be tried or retried in this circuit.

CONCLUSION

In reviewing the record and in making the determination as to the extent to which the decisions of the district court should be upheld or reversed, it is helpful to the perspective to realize, as we observed earlier, that the jury verdict following trial here might have been for the plaintiffs instead of for the defendant. Thus, where judicial discretion is to be reviewed, it must be from the perspective of a trial judge faced with many difficult choices and without the benefit of hindsight. Likewise, where there have been issues which are purely legal in nature, their resolution requires an objective adherence to sound legal and constitutional principles. In a trial of this length and complexity, it is virtually certain that at specific points of the trial one or all of us might have ruled differently on a certain procedure or on the admissibility or inadmissibility of a certain piece of evidence. It is with this realization in mind that we defer in large part to the wisdom and discretion of the trial judge who is provided with a superior advantage point from which he is able to exercise this discretion in organizing the course of trial in a meaningful and practical way. In upholding the result here to the

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[21] Of course, if exclusion were improper, only those plaintiffs who were excluded, the visibly deformed and those younger than ten, would have standing to challenge the exclusion and, if successful, would be the only plaintiffs entitled to a new trial on this ground.

extent we have, it is at least deserving of note that a careful examination of the trial record itself reveals the management of the trial by a judge who does not appear at any time throughout to have sought consciously or unconsciously to have unfairly tipped the scales in favor of one side or the other, but who instead in his rulings appeared to be genuinely concerned with producing a trial that was as fair and free from error as human endeavor could make it. While we must always be conscious of the potential danger of making the trial a sterile exercise of scientific investigation by limiting issues and evidence too narrowly, it is quite evident, through several thousand pages of testimony, that the jury was presented with and bound to appreciate the seriousness of a very real issue of great importance to the parties at suit. In fact, to have broadened the issues beyond that of causation would have occasioned a real risk of overencumbering the jurors and impairing their ability to reach a knowledgeable and intelligent verdict based upon the evidence and upon the law applicable under the appropriate instructions. The result of these proceedings, and of our decision here, will of course mean that for some parties the litigation is concluded, but that for others it may be resumed and continued elsewhere. The reasons for this we have already set forth at length in this opinion and to those we can only observe that such would have been the case in any event had efforts at joinder and then trifurcation not been attempted. This litigation has been substantially advanced by the efforts of the district judge and, we hope, by this decision. We can expect no more at this juncture.

That portion of the district court's order dated August 27, 1985 which remands all cases brought by Ohio citizens originally in state courts is not disturbed. The remainder of that order, which dismisses without prejudice Ohio citizens who brought suit in federal court, is vacated and those cases are remanded to the district court with instructions to enter judgment on the merits and in favor

of the defendant. Finally, those thirteen cases brought by Ohio citizens in federal court over which it is conceded there is no federal jurisdiction shall be dismissed without prejudice.

The judgment of the district court is otherwise AFFIRMED.

JONES, Circuit Judge, concurring in part and dissenting in part. I write separately today for two reasons. First, I write to point out my disagreement with the majority on the exclusion, by the district court, of certain plaintiffs from the courtroom during the twenty-two day jury trial on causation. Secondly, I write to express a few of my concerns regarding the district court's trifurcation order. My opinion, however, is both narrow and focused as I examine only these two issues; issues which possess both great value and import in the functioning of our judicial system. As to all remaining issues raised by this appeal, I concur in the very thorough and well-written majority opinion.

I.

Although I concur in the final result of the majority opinion as regarding the district court's trifurcation order, I do so reluctantly and with serious reservation. However, pursuant to the applicable standard of review, *i.e.*, an abuse of discretion standard which favors the district court's ability and judgment to fairly and expeditiously handle its docket, and to case law within this circuit where such a procedure has previously been approved, *i.e.*, *In re Beverly Hills Fire Litigation*, 695 F.2d 207 (6th Cir. 1982), I agree with the majority that, in this instance, the district court did not abuse its discretion in trifurcating the issues of causation, liability and damages. However, I do express my concerns about the fairness of this mechanism as a tool for handling complex cases such as this. In so doing, I do not re-analyze all of the relevant factors to which

courts look in making their decisions as to trifurcation; Chief Judge Engel has quite thoroughly analyzed those factors. *See supra* pp. 30-59. Instead, I point out potential problems and prejudices that can arise by the use of this procedure.

While it is clear that a trifurcation order such as the one here is not unprecedented, it is equally clear that trifurcated trials are a rarity and have only been approved in the most extreme cases. The fact that trifurcation has rarely taken place, however, does not mean that it is without merit. Rather, since so many potential prejudices loom, trifurcation of issues is limited to rare occasions.

Although I have no problem with the approved trifurcation order in this court's *Beverly Hills* decision, I do become hesitant when that decision is applied, seemingly without reservation, to other cases, such as this one, which are complex in nature. Because I find several distinctions between this case and *Beverly Hills*, I am reluctant to apply such reasoning wholesale. Thus, I find that if *Beverly Hills* is narrowly construed, several problems become apparent with the majority opinion.

First, all of the victims in the *Beverly Hills* litigation were affected by the same event, a disastrous and tragic fire. Thus, the issue of causation could, quite competently, be tried separately from the issues of liability and damages with only a small chance that the plaintiffs would be prejudiced. This was simply because all plaintiffs were affected in the same manner by a unique, single event. Therefore, individual facts about the individual plaintiffs would have had little significance in regard to the question of causation.

The *Bendectin* litigation, however, is quite different. Over 800 plaintiffs, whose mothers took the drug at different times and places and under different circumstances, are involved. As such, a single, unique event such as a fire is replaced by over 800 distinct events that, in all likelihood,

affected the individual plaintiffs in different ways. Although each distinct event involved the ingesting of the same drug, it is hard to believe that *all* 800 plus claims an be tied neatly into one package and satisfactorily resolved by answering of one question, *i.e.*, did Bendectin cause the relevant birth defects? In tying all of these claims together, an argument could certainly be made as to prejudice. That is, by not allowing the plaintiffs to present evidence as to how they were *individually* affected by the drug *could* have resulted in prejudice to them in their attempt to establish the required elements of their case. Indeed, although I concur in the majority's *end* result, I disagree with the language used in reaching the conclusion. The majority opinion refers to the fact that the plaintiffs were not "unduly" prejudiced by the court's trifurcation order. I do not agree that this is the burden plaintiffs must meet to establish an abuse of discretion on the lower court's behalf with regard to a trifurcation order. Rather, my suggestion is that *any* prejudice to a plaintiff in the litigation of his or her case should be enough to hold that the lower court has abused its discretion. I do not agree with the majority that absent a showing of unduly, or excessive, prejudice, the court's order should be upheld. Indeed, this court should define the amount of prejudice that must be demonstrated to establish that a trifurcation order was an abuse of discretion. Such a discussion in this case, however, is without utility. Plaintiffs here simply failed to meet their burden to demonstrate *any* prejudice. That is, plaintiffs lost their case because they failed to establish any link between their birth defects and the drug Bendectin, not because of any prejudice to them resulting from the trifurcation order.

In conclusion, trifurcation orders present fundamental problems of fairness simply because the typical procedure in litigation does not involve the splitting up of a case, element by element, and trying each point to the jury separately. Rather, the plaintiff's entire case is presented

to the jury at once, thereby preventing the isolation of issues in a sterile atmosphere. Simply because a litigant shares his complaint with 800 other claimants is not a reason to deprive him of the day in court he would have enjoyed had he been the sole plaintiff. However, as the majority points out, a trifurcation order is authorized and *necessitated* at some point so as to allow a district court the ability to manage and control the complexities and massive size of a case. The duty of this court, however, is to prevent such a case-management tool from becoming a penalty to injured plaintiffs seeking relief via the legal system.

In this case, after all of these concerns have been considered and accounted for, I agree with the majority that the district court did not abuse its discretion in trifurcating the issue of causation.

II.

While, on the whole, Judge Rubin conducted the potentially mammoth proceedings at issue with great caution, I find that his decision to exclude certain plaintiffs from the courtroom, without first conducting a hearing, was clearly erroneous. By relying upon representations made by the defendant's attorneys, the district court excluded *all* plaintiffs under ten years of age and certain plaintiffs over ten, *i.e.*, those with noticeable deformities, from the courtroom during the jury trial on causation. To make such a decision without first observing or speaking to those plaintiffs is certainly a violation of the principles of due process. Although, as recognized by the majority in this case and this court in *Helminski v. Ayerst Laboratories*, 766 F.2d 208, 213 (6th Cir. 1985), a civil litigant does *not* have an "absolute right to be present personally during the trial of his [or her] case," a decision to exclude a plaintiff from the trial of his or her action must be consistent with due process principles. *Id.* at 216. To be consistent with due process, such a decision *must be* an

informed one. This is necessary to ensure that an excluded party receives a fundamentally fair trial. In meeting this requirement, a district court must take that extra step and conduct a hearing, thereby allowing such plaintiffs to be seen and heard. Such a procedure prevents any *arbitrary* exclusion of a party from the courtroom. In this case, the lower court did not follow such procedures, but instead relied upon representations of the defendant's attorneys. I simply cannot sanction such an action.

Chief Judge Engel, in the majority opinion, correctly notes the above principles and the fact that this court has now required that such procedures be adhere to so as to protect plaintiffs from arbitrary exclusion from the courtroom during the trial of their action. The majority opinion also notes that such procedures were not followed by the district court in this case. Chief Judge Engel points out, however, that the case establishing these procedures, *Helminski,* was not decided until *after* the district court had made its decision to exclude certain plaintiffs and *after* Judge Rubin had already conducted a twenty-two day jury trial on the issue of causation. While I concur in the praise offered by the majority of the district court's efforts to manage this complex action, I disagree with the majority as to this issue. Rather, I find that the trial court, in this regard, violated the plaintiffs' constitutional due process rights. Furthermore, I disagree with the majority's proposition that *Helminski,* a case which would quickly dispose of this issue, was an unprecedented decision and thus should not be applied retroactively to this case. Indeed, this is the bulk of my disagreement since all three judges on this panel would seemingly agree that the record shows that the district court certainly did not follow the required *Helminski* procedures, discussed indepth in the majority opinion and not repeated here. *See supra* pp. 64-70.

Because I disagree with the majority's finding that no case law existed within this circuit or the Supreme Court, prior to *Helminski,* which would have placed the district

court on notice as to its duties vis-a-vis the exclusion of plaintiffs from the courtroom, thereby precluding the application of *Helminski* to this case because of the applicable *Chevron* [*Chevron Oil Co. v. Huson*, 404 U.S. 97 (1971)] rules on retroactivity, I respectively offer my dissent.

A.

I believe that prior to *Helminski* authority and precedent existed which required lower courts to at least allow a plaintiff, prior to being excluded from the courtroom, during his or her trial, the opportunity to be seen and heard. Indeed, I not only find that *Helminski* was not unprecedented, I also find that that decision was simply a continuation and affirmation of the prior case law setting forth principles of procedural due process. Thus, these principles not only were in existence, but also required lower courts to do more than simply rely upon representations made by opposing parties in such important and fundamental decisions. Accordingly, the excluded plaintiffs' due process rights were violated by the lower court's actions with regard to this issue.

I find support for my conclusion specifically in *Helminski*. Although the majority opinion correctly notes that the decision in *Helminski* is basically supported by decisions from state courts, it fails to note that the *Helminski* court cited as support, for the fundamental notions of due process set forth within that opinion, decisions from this circuit and the Supreme Court. Although the district court in this instance should not be held to a standard where it should have known all the nuances of what due process required before it could exclude a party from the courtroom during the trial of his or her action, it certainly must be held to a standard requiring it to follow and respect a litigant's due process rights to a fundamentally fair trial.

No language in *Helminski* is indicative of the fact that this decision is one of first impression within this circuit.

Rather, the opinion draws from a variety of Supreme Court and circuit courts of appeals' due process opinions in holding, ultimately, that a hearing is necessary prior to the time a party may be excluded from the courtroom. Indeed, the court cites to a prior Sixth Circuit opinion, *Drayton v. Jiffee Chemical Corp.*, 591 F.2d 352 (6th Cir. 1978), for the proposition that:

> Exclusion of a party who is able to comprehend the proceedings and aid his attorney would infringe upon the "fundamental standards of fairness which every litigant before a federal court has a right to expect," and hence, would constitute a deprivation of due process which could be remedied only by granting a new trial.

Helminski, 766 F.2d at 218 (citing *Drayton*, 591 F.2d at 361).

Based upon the *Helminski* court's language and its cited precedent, I find nothing that would allow me to hold that that decision was such a break from past law so as to prevent its retroactive application to this case. Rather, I find that the district court should have been on notice as to the fact that its particular actions were unconstitutional.

B.

The majority also lists several equitable reasons why *Helminski* should not be applied to this case, *i.e.*, a twenty-two day jury trial had been completed and a verdict rendered before *Helminski* was decided. Surely such reasoning must fold to the fundamental due process rights of litigants to receive a fair trial. Indeed, because it is not evident that all excluded plaintiffs could *not* have understood the proceedings and could *not* have a aided their counsel in presenting their case, *i.e.*, *Helminski* requirements, the excluded plaintiffs' due process rights to a fundamentally fair trial were violated. Thus, the plaintiffs were prejudiced by the court's failure to make the necessary findings re-

garding their ability to comprehend and aid in the presentation of their case to the jury. Because I find that it is not evident that the plaintiffs would have been excluded from the courtroom if the proper procedures had been adhered to by the district court, I find that such error is not harmless and therefore constitutes reversible error.

Therefore, because the decision in *Helminski* was a continuation of this court and the Supreme Court's prior due process analyses, it should be applied retroactively to this case, thereby resulting in a finding that the lower court erred in arbitrarily excluding certain plaintiffs from the courtroom without the benefit of an opportunity to be heard and seen. As noted by the majority, the presumption is that a newly announced rule of law will apply retroactively and the burden of persuasion to demonstrate that such an application is unjust is on the party asserting prospective-only application. *See Cochran v. Birkel*, 651 F.2d 1219, 1223 n.8 (6th Cir. 1981). Here, that burden has not been met. The lower court made no findings, with support, as to whether the plaintiff's presence would prejudice the jurors or as to whether the excluded plaintiffs would have been able to comprehend the proceedings and aid their counsel in presenting their case. Such findings are requirements of due process. Thus, I find that the district court's error in this regard should allow those plaintiffs who were arbitrarily excluded from the courtroom during the trial of their action an opportunity to have another day—a fundamentally fair one—in court. Therefore, I respectfully dissent.

Food, Drug and Cosmetic Act

52 Stat. 1040 § 201(n)
[21 U.S.C. § 321(n)]

§ 321. Definitions; generally
For the purpose of this chapter—

(n) If an article is alledged to be misbranded because the labeling or advertising is misleading, then in determining the labeling or advertising is misleading there shall be taken into account (among other things) not any representations made or suggested by statement, word, design, device or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under the conditions of use prescribed in the labeling or advertising thereof or under such conditions or use as are customary or usual.

52 Stat. 1040 § 502(a), f(f)(2) and (j)
[21 U.S.C. § 352(a), (f)(2) and (j)]

§ 352. Misbranded drugs and devices
A drug or device shall be deemed to be misbranded—

False or misleading label

(a) If its labeling is false or misleading in any particular.

* * *

Directions for use and warnings on label

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be

dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and from, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

* * *

Health-endangering when used as prescribed

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

FILED OCT 11 1988

MDL Docket No. 486

NOTICE OF APPEAL

IN RE: RICHARDSON-MERRELL, INC., "BENDECTIN" PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 486

THIS DOCUMENT APPLIES TO:

ALL CASES SUBJECT TO THE JUDGEMENT ENTERED MARCH 22, 1985 IN THE CONSOLIDATED CAUSATION TRIAL AND;

ALL CASES INDIVIDUALLY LISTED HEREIN WITHOUT LIMITATION ON ANY CASE NOT LISTED BUT SUBJECT TO JUDGMENT:

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Annette-Williams, et al.	C-1-85-0717

Plaintiffs-Appellants,

vs.

MERRELL DOW PHARMACEUTICALS, INC.,
(formerly known as)
RICHARDSON-MERRELL, INC.
2110 East Galbraith Road
Cincinnati, Ohio 45215

Defendants.

Notice is hereby given that all Plaintiffs, subject to the Judgment entered March 22, 1985, and including but not limited to those Plaintiffs individually listed herein, hereby appeal to the United States Court of Appeals for the Sixth Circuit from Final Judgment entered September 18, 1985 in accordance with the Courts Order denying Plaintiffs

Motion for a new trial and for Judgment Non Obstante Verdicto.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document has been served upon all counsel of record this 11th day of October, 1985.

/s/ Stanley M. Chesley
Stanley M. Chesley

NO. 88-704

SUPREME COURT, U.S.
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CLERK

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1988

IN RE: BENDECTIN LITIGATION

SARAH ANN HOFFMAN, ET AL.
ELIZABETH ANN DAVIS, ET AL.
AND SHANE ROSS WOOD, ETC., ET AL.
Petitioners

vs.

MERRELL DOW PHARMACEUTICALS INC.
Respondent

BRIEF FOR RESPONDENT IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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CORPORATE AFFILIATIONS OF RESPONDENT

Respondent Merrell Dow Pharmaceuticals, Inc. is a subsidiary of The Dow Chemical Company. Its subsidiaries and affiliates which have securities in the hands of the public are the following:

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I. STATEMENT OF THE CASE

A. ORIGIN AND FILING CHRONOLOGY OF THE BENDECTIN CASES IN ISSUE

The Petitioners were plaintiffs in the U.S. District Court for the Southern District of Ohio, Western Division, in a consolidated trial that resulted in a verdict and judgment for the Respondent, Merrell Dow Pharmaceuticals Inc. They seek review of the decision of the U.S. Court of Appeals for the Sixth Circuit, to the extent to which it affirmed the defense judgment of the district court. The consolidated trial concerned claims that approximately 1160 children (of whom 82 were deceased at time of trial) were afflicted with birth defects as a result of their mothers' ingestion, during pregnancy, of Respondent's pharmaceutical product, Bendectin.

Some eight hundred Petitioner families filed their claims in federal court in Ohio.[1] The remaining Petitioner families, after transfer of their cases to the Southern District of Ohio for discovery by the Judicial Panel for Multidistrict Litigation, voluntarily sought consolidation for trial in Ohio.

The fact that the Petitioners are so numerous results, in large part, from the district court's decision of April 12, 1984, pursuant to Rule 42(b), Fed. R. Civ. P., to initially try the question whether Bendectin, taken by a human mother in therapeutic doses during the period of embryonic organogenesis (the period of gestation during which the organs are formed) causes human birth defects. This was the so called "trifurcation order." The streamlining effect which it had on initial trial preparation caused the Ohio litigation to become a nationwide magnet for *new* Bendectin plaintiffs, seeking consolidation with the pending federal action. To

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[1] 72 lawsuits involving 147 children were filed in state court in Ohio, and subsequently removed to federal court. All but 21 of those children were also plaintiffs in parallel suits filed originally in federal court. Such duplicative filings introduce some uncertainty into Respondent's estimates of the number of Petitioners in each category.

understand the benefits of the procedure which the district court chose requires an appreciation of issues which arise in the more routine trial of an individual Bendectin case.

Birth defects are, unfortunately, a relatively common occurrence, being seen in approximately 3 to 7 percent of births. The causes of most birth defects (around eighty percent) are unknown. In the occasional instance, the cause can be identified as genetic, environmental or as the ingestion by the mother of some injurious agent. Bendectin was a widely used prescription medicine for alleviation of nausea and vomiting in pregnancy. It has been used since 1956 in some 18 million pregnancies in the United States alone. Its wide usage over so many years made it inevitable that many women who had taken Bendectin would by chance deliver babies with birth defects, merely as a reflection of background incidence. Bendectin is and has been approved by the FDA since 1956, and has been the subject of intense published scientific study concerning its safety for the unborn child.

The "trifurcated" causation trial postponed (and ultimately eliminated) the need to consider certain plaintiff-specific causation issues. These include the following:

1. Did the mother actually take Bendectin? — While complaints invariably allege the ingestion of Bendectin during pregnancy, the medical records of the mother or baby sometimes contradict this contention, reporting the absence during pregnancy of "morning sickness" (the sole affliction for which Bendectin was indicated) or specifically recording that no medication was taken during pregnancy. Since Bendectin is a prescription medicine, lack of any physician or pharmacy records of a prescription is evidence of non-ingestion.

2. If the mother took Bendectin, did she take it during the criticial period of pregnancy? — Sometimes a plaintiff mother reports a first ingestion of Bendectin at a point in pregnancy by which it is scientifically demonstrable that the deformity with which her child is afflicted was already present. This circumstance has resulted, in some cases, in summary disposition.

3. Is there a genetic cause for the birth defect? — Some birth defects are caused by specific chromosomal or genetic characteristics of the parents. Detection of these factors requires a genetic examination and evaluation of the parents and child and collection of information regarding family history.

4. Was the mother exposed to some known teratogenic[2] agent? — Approximately twenty-five substances are recognized as human teratogens.

None of the foregoing inquiries would answer the broader question whether Bendectin, used as directed, causes human birth defects. However, each Petitioner was obliged to demonstrate the affirmative of such question by a preponderance of the evidence. Evidence on the issue is voluminous, detailed and technical.

"Trifurcation" of the causation issue was appealing to plaintiffs for several reasons. It permitted pooling of counsel's talents and plaintiffs' resources. Late-arriving plaintiffs could "coat tail" on the trial preparation of a small group of plaintiffs' lawyers who had managed trial preparation from the beginning. The stay on discovery (discussed below) would forestall development of the facts in individual cases and postpone the associated discovery burdens of plaintiffs and their individual counsel. A plaintiffs' victory in the initial trial would dramatically advance prospects for a favorable settlement for any plaintiff *whose case had been consolidated.*

New plaintiffs flocked to join the "trifurcated" lawsuit. Some successfully sought consolidation while the trial was actually underway. The trial was originally scheduled for June 11, 1984. However, Respondent negotiated a tentative settlement agreement with plaintiffs through the Plaintiffs' Lead Counsel Committee (PLCC), a panel of five attorneys elected from their numbers by plaintiffs' counsel to prepare and try

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[2] Dorland's Illustrated Medical Dictionary, 24th Edition, defines a "teratogen" as: "an agent or factor that causes the production of physical defects in the developing embryo."

the case. On June 18, 1984, the district court issued an order certifying a Rule 23(b)(1) non-opt-out class of plaintiffs for settlement purposes, an essential element of the settlement. Certain plaintiffs took exception to the settlement agreement and shortly secured a writ of mandamus from the Sixth Circuit Court of Appeals vacating the order certifying the settlement class.[3]

While the settlement was pending, Petitioners successfully sought a stay of all further discovery for 120 days, to expire on December 28, 1984. Petitioners thereafter sought a stipulated extension of the discovery stay until July 1, 1985, long after the anticipated completion of the initial phase of trial, then scheduled to begin in February 1985. Respondent, in light of the circumscribed nature of the initial "trifurcated" trial, (and at Petitioners' request) agreed to forego any discovery prior to the first stage of trial, regarding the claims of the 561 Petitioner families who joined the consolidated suit after discovery was first stayed.

The "trifurcation" order permitted the number of plaintiffs to more than triple before trial, without either delaying that trial or enlarging the proof to be offered by either side. Of plaintiff families who filed their Bendectin claims in Ohio federal courts after the issuance of the order of trifurcation, more than 400 were represented by one or more members of the PLCC.

All Petitioners who had sued in federal courts outside Ohio were, *after* trifurcation was ordered, given the choice whether their cases would be remanded for disposition to the districts of origin or consolidated for the "trifurcated" trial. Each declined the district court's offer of a remand to their originally chosen federal district.[4] Thus, more than eight hun-

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[3] The abortive settlement was not a major factor in attracting new plaintiffs. Only 84 Petitioners filed suit in the district court while it was pending.

[4] Numerous other plaintiffs declined to participate and their cases were remanded to their districts of origin for the individual disposition which Petitioners now maintain was unlawfully denied them.

dred either accepted consolidation without objection after the trifurcation order was entered or declined the opportunity for remand.[5] If any Petitioner was dismayed by the trifurcation order or considered such a trial format unfair, the secret was well kept from the hundreds of additional plaintiffs who joined thereafter, mostly represented by PLCC members.

B. THE "TRIFURCATION" ORDER: DOES BENDECTIN CAUSE BIRTH DEFECTS?

The verdict consisted of the jury's negative answer to a special interrogatory under Rule 49, Fed. R. Civ. P. "Have the Plaintiffs established by a preponderance of the evidence that ingestion of Bendectin in therapeutic doses during the period of fetal organogenesis is a proximate cause of human birth defects?" This ended the trial. The district court, on March 12, 1985, entered a judgment for the Defendant.

The concept of a separate trial on the threshold question whether Bendectin causes birth defects originated long before. At a status conference on July 1, 1983, the Chairman of the PLCC proposed trying 15 to 20 selected cases on the common issue of causation:

> We would try on the common issue of causal connection, is this a teratogen, and once we had a result as to those cases, we could then branch out, and as far as I am concerned, Your Honor, once liability, if it's not established, we are over. If it is established, then the damage thing can be done in some kind of other concept of funds for different groups of persons.

Transcript of Status Conference of July 1, 1983.

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[5] As their numbers grew, plaintiffs several times sought reconsideration of the trifurcation order but, except for certain plaintiffs in transferred cases, no Petitioner ever objected to the *consolidation* of his suit for trifurcated trial. The later-arriving plaintiffs clearly wished to preserve a claim of error notwithstanding their judgment that this arrangement was perferrable to their other litigation options.

Soon after, in a memorandum dated September 29, 1983, the PLCC suggested, among other issues suitable for a consolidated trial: "Whether Bendectin is teratogenic." They further wrote:

> But since, as the court recognizes, success upon one or more of the following issues is "essential to the success of any Plaintiffs' claim" consolidated trial upon these issues could accomplish a great savings of time and effort and avoid needless repetitive litigation . . . Should the Plaintiffs succeed upon any one of these enumerated issues, then the actions could proceed individually upon issues related to individual cases. In this manner, the interest of convenience and economy Rule 42 is designed to promote would be served.

Plaintiffs' response to court's order to show cause.

On December 29, 1983, the district court issued an order listing the common issues which would be tried in the consolidated cases beginning June 11, 1984. This was amended on April 12, 1984. The court stated, in part:

> The trial of this matter on liability issues will be trifurcated and questions relating to causation will be considered first. A jury determination on such issue will be made before any other matter is considered. Should Plaintiffs prevail on causation issues, the jury will hear and then consider the other matters listed herein. A Defendant's verdict on the issue of causation will terminate the trial.[6]

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[6] The earlier order had included the issues whether Bendectin was "unreasonably dangerous" and of the adequacy of warnings provided by Respondent. These questions clearly required a threshold finding of what "danger," if any, existed.

C. THE DISTRICT COURT'S ORDER EXCLUDING FROM THE COURTROOM CERTAIN MINOR PARTIES IN INTEREST

The district court, on February 19, 1985,[7] after the trial was underway, journalized an order precluding children with visible deformities and those under 10 years of age from being present in the courtroom. The court had been extensively briefed as to the different types of birth defects in issue and had, in December, 1983, been provided with a list of birth defects alleged by those plaintiffs who were then before it. The trial court reserved, within the courthouse, a room equipped with closed circuit television. (Appendix to Petition, page 67a) By this means, any children who wished to witness the trial could do so with their parents or other care givers. Telephone communications were established between the television viewing room and the PLCC in the courtroom. Representatives of plaintiffs' counsel were to be present in the viewing room to assist in any attorney-client communications which were desired. No parent or guardian of a minor plaintiff was affected by the exclusion order, nor was any minor plaintiff who was not within its terms.

The record does not show which children who were described by the order would otherwise have attended the trial. Petitioners' counsel made no move to argue that specific children could attend the trial without danger of prejudice or

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[7] The written exclusion order preceded by 6 days a public event which became known as "Bendectin Justice Day." This was a march to and around the federal courthouse in Cincinnati by a number of families including children with birth defects. Having learned that this event was in the offing, the district court ordered the jury sequestered from Sunday afternoon, February 24, 1985 until Wednesday, February 27. The demonstration occurred on Monday, February 25 and was, that morning, discussed by the court with counsel. Petitioners' counsel requested that the jury be told that they, the attorneys, were not responsible for the demonstration. The court declined to inform the jurors as to the cause of the sequestration order but only advised them that they were not physically endangered. At best, this episode confirms that not all claimants were under their counsel's direction or were inclined to let the jury decide the case solely on the evidence.

disruption. The emphasis of argument was that the order was erroneous, not that it was overbroad. Including the adult plaintiffs, the trial involved between 2000 and 3000 plaintiffs. It was always clear that most of these people would not attend the trial.

In March 1984, the district court, noted that its courtroom could accommodate no more than 100 plaintiffs' attorneys and 50 plaintiffs. Counsel were directed to promptly advise the court if additional space would be required. The population of plaintiffs was then less than one-third what it would be by trial. At one point, the district court discussed the possibility of renting the Cincinnati Convention Center, if necessary, to accommodate those wishing to attend. Nonetheless, Petitioners' counsel never advised the court that the normal courtroom would be inadequate. Obviously few plaintiffs, adults or children, wished to follow the trial in person from day to day.

On March 19, 1984 (when only about 260 Petitioners had filed their suits in federal courts in Ohio), the district court orally disclosed its intention to exclude from the courtroom children who were "not of an age where that child can meaningfully communicate with a lawyer and assist in the trial. . ." In response, one member of the PLCC suggested that the court select *at random* five children possessing birth defects from each of eight categories of birth defects in issue.[8]

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[8] These categories were:

a) limb defects
b) other muscular/skeletal defects
c) central nervous system defects
d) heart defects
e) head deformities
f) respiratory defects
g) gastrointestinal defects
h) genital urinary defects
i) death

Of the eight categories involving living children, only categories a, b, and e clearly suggested that such defects might be *visible*. Of course, the exclusion order is irrelevant to any case involving a deceased child.

Only these children would attend the trial. While the court declined this suggestion, the proposal revealed that no importance was attached to attendance at trial by any particular minor plaintiff.

D. HISTORY OF THE JURISDICTIONAL ISSUE

Of those roughly two hundred Petitioners who are situated to present Petitioners' third question of law, (because they were, at the filing of their suits in federal court, of nondiverse citizenship with Respondent) the earliest case was filed in 1981 and the last (involving 7 Petitioners) was filed and voluntarily consolidated when the trial, itself, was halfway to completion. On March 12, 1985, a jury verdict for the Respondent was rendered and a judgment entered accordingly. On March 22, 1985, Petitioners filed a motion for a new trial and other relief.

On July 15, 1985, before Petitioners' motion for new trial had been ruled upon, the court of appeals issued its decision (discussed hereinafter) in two cases brought by other Bendectin plaintiffs, *Thompson* v. *Merrell Dow Pharmaceuticals Inc.* and *McTavish* v. *Merrell Dow Pharmaceuticals Inc.*, 766 F.2d 1005 (6th Cir. 1985). Pursuant to that opinion, the district court, *sua sponte* on August 27, 1985, issued an order for the dismissal or remand of 300 Bendectin cases filed in the district court or removed from Ohio state courts wherein plaintiffs were citizens of Ohio.[9] On August 30, 1985, before the dismissal/remand order by the district court had been implemented, Respondent moved for a stay of that order to per-

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[9] Respondent believes that the district court initially drew the erroneous conclusion that the Sixth Circuit in *Thompson* had *ruled* that the FDCA permits no private claims and that Petitioners' *federally-filed* complaints alleging such private claims could not support jurisdiction. As noted hereafter, neither the Sixth Circuit nor this Court made such ruling in *Thompson*. The district court never issued any decision on its reconsideration of the jurisdictional issue because the Petitioners' appeal placed this issue before the court of appeals.

mit briefing of the jurisdictional issues. On September 3, 1985, the district court granted the requested stay, effectively agreeing to reconsider the order. On September 17, 1985, with the stay of the dismissal/remand order still in effect, the district court denied Petitioners' motions for new trial and JNOV. On October 11, 1985, Petitioners filed their notice of appeal to the Sixth Circuit.

On October 11, 1985, Respondent filed with this Court its petition for certiorari to the Sixth Circuit in the *Thompson* case. Two questions were presented by that petition:

1. Where a plaintiff alleges that a violation of a specific federal regulatory statute constitutes a rebuttable presumption of negligence and that such a violation directly and proximately caused injury to plaintiff, does such claim "necessarily depend" on resolution of an issue of federal law, so as to vest subject matter jurisdiction in the District Court?
2. Where a claim which "necessarily depends" on resolution of an issue of federal law is joined with other claims of purely local law which would, if the plaintiff prevails, obviate the federal question, does the pendency of such purely local claims deprive the District Court of jurisdiction?

On December 2, 1985, this Court granted Respondent's petition for certiorari in *Thompson*. *Merrell Dow Pharmaceuticals Inc.* v. *Thompson*, 474 U.S. 1004 (1985). The district court had not yet ruled on the arguments of the parties concerning that court's *sua sponte* order of August 27, 1985 dismissing or remanding the 300 cases. Petitioners and Respondent had briefed the issues and the stay of the dismissal/remand order was still in effect. Respondent had briefed certain grounds for federal subject matter jurisdiction (hereafter discussed) which were not within the grant of certiorari by this Court in *Thompson*, but which would, as it maintained, independently sustain subject matter jurisdiction over the 300 cases.

On January 6, 1986, the district court modified,[10] in part, its dismissal/remand order of August 27, 1985, but continued the stay of its order of August 27, 1985 as to the great majority of the 300 cases. Thereafter, the court of appeals reversed that order as to federally-filed cases, but left undisturbed the remand portion of the order.

II. SUMMARY OF ARGUMENT

Petitioners, themselves, suggested that the question whether Bendectin causes birth defects was appropriate for a consolidated trial, and that such a trial could significantly advance the litigation. Though always protesting "trifurcation" of the case, new plaintiffs rushed to join the litigation, obviously anticipating success rather than fearing any perceived unfairness in the trial format. Petitioners were pleased to join forces to show that Bendectin was injurious, but now claim that it was unfair that they were forbidden to bolster their inadequate scientific evidence by vilifying the Respondent before the jury. The district court's decision to first try the most difficult common issue of all the cases was a sound exercise of discretion in a case in which emotional appeals might easily have overcome the evidence.

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[10] As to certain cases among the 300, the district court ruled that reconsideration need not await the decision of this Court in *Thompson*. The district court ruled that the cases of Michael Huseman, U.S.D.C. No. C-1-85-0692, and Shawn Beggs, U.S.D.C. No. C-1-85-0717 had previously been voluntarily dismissed with prejudice by the plaintiffs and were erroneously included in the August 27 order. A similar ruling was made with respect to the case of Elizabeth Newman, U.S.D.C. No. C-85-0716. As to the case of Kelly Mullanney, U.S.D.C. No. C-85-512, the district court determined, per *Grubbs* v. *General Electric Credit Corp.*, 405 U.S. 699 (1972) that diversity of citizenship was an adequate basis for jurisdiction. Likewise in Kimberly Wykoff, U.S.D.C. No. C-82-1039, Robbin E. Thomas, U.S.D.C. No. C-1-81-0069, Irving Rosenstein, U.S.D.C. No. C-1-82-0964 and Troy Hill, U.S.D.C. No. C-1-82-0224, the court noted that diversity of citizenship existed when the complaints were filed. These cases were, accordingly, removed from the list of cases to be dismissed for want of subject matter jurisdiction.

Certain Petitioners (who are unknown and unidentifiable) claim that the district court's order excluding small children and deformed children from the courtroom denied their rights of due process in the trial of their claims. Such Petitioners, nonetheless, declined to offer evidence of their individual circumstances because such details were irrelevant to the issue then on trial. Even those excluded from the courtroom had as full an opportunity to witness and participate in the trial as their courtroom presence would have permitted. All that was denied them was the opportunity to influence the jury by the emotional impact of the children's presence or to distract the jury from the evidence in hope of a result-oriented verdict. The district court's order merely protected Respondent's right to a verdict based solely on the evidence without impeding either Petitioners' presentation of proof or their participation in their trial.

Certain Petitioners sued Respondent asserting private claims under the Food, Drug and Cosmetic Act. Having been unsuccessful at trial, they now attack the legal sufficiency of those claims, contending that their chosen forum lacked jurisdiction. They do not contend that their federal claims were frivolous but only mistakenly argue that *subsequent* decisions by this Court and the court of appeals declared such private claims unavailable under the FDCA. However, the availability of such private FDCA claims is an open question, as it was when Petitioners' federal claims were filed. In any event, the supposed legal insufficiency of Petitioners' federal claims does not destroy the subject matter jurisdiction of the district court.

III. ARGUMENT

A. SEPARATE TRIAL OF THE QUESTION WHETHER BENDECTIN CAUSES BIRTH DEFECTS WAS CONDUCIVE TO EXPEDITION AND ECONOMY, AVOIDED PREJUDICE TO ANY PARTY AND WAS WITHIN THE DISCRETION OF THE DISTRICT COURT.

Petitioners seek a ruling not merely that "trifurcation" was unfair in their case, but that it is *always* unfair. They urge that the dangerous character of a product is not an issue that may *ever* be separately tried in a fair and just manner. In effect, Petitioners ask a modification of Rule 42(b), Fed. R. Civ. P. which permits any "separate issue" to be tried separately in the trial court's discretion. To the extent to which it is based other than on mischaracterization of the record, Petitioners' argument lends no support to their broad proposition and, in this case, confirms the wisdom of the procedure chosen by the district court and approved by the court of appeals.

Petitioners still maintain that no "fact witnesses," as opposed to expert witnesses, were permitted to testify. The court of appeals found this argument unsupported by the record. (Appendix to Petition, pp. 55A, 56A.) It was always contemplated by all concerned that the initial phase of trial would not focus on the circumstances of the individual plaintiffs. Without this understanding, Respondent's agreement, at Petitioners' request, to postpone any discovery regarding the majority of the plaintiffs (who joined the lawsuit after the discovery stay of August 30, 1984) would have been unthinkable. When, despite the discovery stay, plaintiffs announced their intention that their expert witness, Dr. Alan K. Done, display certain plaintiffs to the jury by way of explanation of his opinion, Respondent sought an order *in limine* precluding such testimony. The district court *denied this motion,* but the Petitioners never offered such testimony at trial.

Petitioners *never* disclosed even a desire that the first trial phase focus on the individual circumstances of each of over 1000 children. This limitation permitted and encouraged the majority of the Petitioners to join the consolidated case after the trifurcation order was entered.

Petitioners imply that photographs or representations of the birth defects at issue were excluded from evidence by the court. This is simply untrue. As the court of appeals noted:

> In this case, Plaintiffs correctly observe that there was no evidence admitted as to the physical condition of individual Plaintiffs. However, that was not because the judge was unwilling to let it in. At trial, attorney Chesley [PLCC Chiarman] recognized that he was not precluded from introducing photographs, diagrams, or skeletons.

Appendix to Petition, pp. 72-73.

There was never an *offer* of any evidence of the personal circumstances or history of any Petitioner or of any particular plaintiff's defects. Though the issue never arose at trial, admission of such evidence would likely have been prejudicial to the Respondent, because of the agreed stay on discovery. Respondent knew literally nothing about the majority of the Petitioners who had joined the consolidated action after August 30, 1984. It did not know whether the mother had taken Bendectin (or when) nor whether the family had a history of genetically-caused defects. Petitioners' failure to offer evidence concerning individual plaintiffs, even after the district court had refused to preclude it, reflected a tacit understanding of the scope of the trial's first phase. The arrangement was hardly one-sided. It was because the trial format permitted new plaintiffs to join the action without any change in trial strategy or tactics *by either side* and without any discovery by the Respondent that the numbers of plaintiffs grew so prodigiously up to and even during the trial.

The filing chronology indicates that Petitioners' counsel were beating the bushes to enlist as many plaintiffs as possible

to join in the trifurcated trial and, thus, to have the benefit of a judgment in their favor that Bendectin causes birth defects. Respondent was subject to suit in any state where Bendectin allegedly caused an injury. Only some two hundred Petitioner families were Ohio citizens. Why did the more than eight hundred Petitioner families flock to Ohio rather than file their cases at home? They did so because they considered the "trifurcated" Bendectin trial to be a gold mine and wanted to stake their claims. They now regret their decision because the verdict was against them.

Petitioners' assertion that the trial was characterized by a "sterile, laboratory type atmosphere" and by "inappropriate abstraction" is explained by the remainder of their petition. They bemoan the fact that they were not permitted to show that Bendectin causes birth defects by attempting to prove that the Respondent is an evil company. Petitioners were not permitted to try the Respondent for its association (as a licensee of an European company) with the sensational Thalidomide episode or for alleged misdeeds with respect to drugs *other than Bendectin*. Petitioners' objection to "sterility" is that they were forbidden to introduce the contamination of evidence which, though unrelated to causation, might induce the jury to endorse otherwise inadequate proof on causation. The very arguments of Petitioners against trifurcation demonstrate that the district court knew its business in separately trying Bendectin's safety. Not only did trifurcation avoid prejudice to Petitioners, it prevented that prejudice against Respondent which Petitioners' trial team stood ready to foment in the jury. Furthermore, as the court of appeals noted: "If anything, the narrowing of the range of inquiry through trifurcation substantially improved the manageability of the presentation of proofs by both sides and enhanced the jury's ability to comprehend the causation issue." (Appendix to Petition, p. 51.)

Petitioners finally criticize the use by the court of appeals of the phrase "undue prejudice" in evaluating the discretionary decision of the district court. Even the dissenting

panel member who raised this issue concurred with the majority that the district court's order of "trifurcation" was within its discretion. (Appendix to Petition, p. 77) Respondent urges that the panel below was unanimous in its reasoning on trifurcation as well as its conclusion. The phrase "undue prejudice," like "unfair prejudice," as used in Federal Evidence Rule 403, is hardly meant to suggest that some lesser degree of prejudice is "due" or "fair." The sense of the majority opinion, like that of the dissent, is that *no* prejudice was inflicted by the trifurcation order.

B. THE DISTRICT COURT'S DECISION TO LIMIT PLAINTIFFS OF TENDER YEARS AND THOSE VISIBLY DEFORMED TO TELEVISION VIEWING OF THE TRIAL REASONABLY BALANCED THE RIGHTS OF PETITIONERS WITH THOSE OF RESPONDENT.

All minor Petitioners who were able to come (or be carried) to the courthouse were allowed to see and hear *the entire trial* and to talk with their counsel during trial. An unknown few were limited to doing so by means of closed circuit television and a telephone hook up. This very significant fact is omitted from the petition. Petitioners do not contend that this arrangement was at all inferior to physical courtroom presence as a means to provide to their counsel such information or assistance as these children had to give. The only benefit of courtroom attendance which was denied any Petitioner was a chance for the jury to see them during trial, and alternate its attention between them (and their physical defects) and the evidence being presented. This trial did not concern the extent of Petitioners' injury nor even whether Bendectin had caused *these particular* injuries. No evidence was *offered* of any Petitioner's injury or history, even by photographs. No Petitioner was offered as a witness, including any parent or guardian. Only their claim that Bendectin was an injury-causing product was, as yet, on trial.

Thus, the only "right" which Petitioners can claim to have been denied is the "right" to sway the jury's fact-finding by that sympathy which deformed or crippled children invariably arouse or to distract the jury from the evidence. Who among the Petitioners wished to exercise these supposed "rights" is undiscoverable from the record.

Petitioners cannot show who among them is personally aggrieved by the exclusion order, that is, who would have attended the trial in the courtroom, but for the order. They cannot say who wished to attend, or could have attended. Most voluntarily consolidated their suits for trifurcated trial after the district court had declared on the record its intention to exclude children too young to assist counsel. Such statement predated even the trifurcation order. This fact and the "random selection" proposal advanced by the PLCC when the district court's intention was revealed, (discussed at page 8, above) shows that few, if any, plaintiff children would have attended. To have identified those children able and desirous of attending would, of course, also have identified the remainder (and majority) as free of any practical impact from the order, and denied those absentees the benefit of this claim of constitutional error. To have standing to appeal, any Petitioner must show "distinct and palpable injury to himself." *Warth* v. *Selden*, 422 U.S. 490, 501 (1975).

Petitioners imply that they *all* deserve a new trial because of the exclusion order. However, no parent or guardian was excluded from the trial (though few attended) nor was any child who was at least 10 years old excluded, save those with visible defects. There is no logic in contending that a party who was not excluded is entitled to a new trial because others were excluded wrongfully. At most, only those unlawfully excluded can rely upon this claim of constitutional error.

Petitioners complain that the district court's exclusion order was entered without a hearing at which the excluded children were heard and seen by the court. However, they neither asked for a hearing for this purpose nor offered any evidence that the court's fears of prejudice or disruption were un-

founded. Allowing a scant 15 minutes per child, 36 trial days or about 7 weeks would be needed for hearings on the 1000 living plaintiff children. Of course, presumably fewer than that were afflicted with visible birth defects or under 10 years old at the time of trial.

However, this was as unnecessary as it was impractical. Only those able and wishing to attend needed a hearing of any sort. As noted, these individuals cannot be identified. This information is not only necessary to a determination of who might have been prejudiced by the order; it is necessary to knowing who was affected *at all*. Both the Petitioners and the dissenting judge in the court of appeals ignored the impossibility of determining, on this record, who among Petitioners would even have standing to claim a new trial by reason of the exclusion order. Petitioners alone could have created such a record and declined to do so.

Since Petitioners ask for a retrial based upon the exclusion order, it is worth considering how the district court might handle the exclusion issue on retrial. Respondent would, of course, maintain, as it did before, that the children cannot help their case (or their counsel) other than by enlisting the jury's sympathy, and that those with visible deformities would influence the jury to decide the case on a basis other than the evidence. The conduct of the "hearing" which Petitioners only now demand would pose numerous theoretical questions in anticipation of a new trial. If any particular child were deemed excludable at a retrial, would there be any reason for a retrial as to his claims? If a child plaintiff is found not excludable at retrial but declines (or is otherwise unable) to attend, does the retrial of his case serve any purpose other than to give him a second bite at the apple?

Petitioners claim that unknown and unidentified children were denied their "due process" rights to a fair trial. They do *not* urge that they were denied the right to witness the trial or to assist counsel (assuming, without support in the record, that they had the capacity to assist). Whoever these children were, they had the means to do *both*. All that was denied was

the chance to have the jury see such children as a focus for sympathy, not as witnesses or as human demonstrative evidence (neither of which was attempted).

Petitioners misreport the outcome of *Helminski* v. *Ayerst Laboratories*, 766 F. 2d 208 (6th Cir. 1985), *cert. denied*, 474 U.S. 981 (1985), maintaining that it stands for the proposition that exclusion of a plaintiff without a hearing at which he is seen and heard by the court mandates reversal and new trial. In fact, the Sixth Circuit in *Helminski* found that such a hearing was called for (and erroneously denied the minor plaintiff there), but nonetheless *affirmed* the defense judgment (Appendix to Petition, pages 69-70a). The court held that the inability of the minor plaintiff to comprehend the proceedings in his case or to assist counsel warranted the conclusion that his absence had not affected the outcome. A strict application of the principles of *Helminski* to this case would warrant affirmance of the defense judgment.

In considering Petitioner's motion for new trial, the district court specifically inquired of their counsel whether the presence of any minor plaintiff in the courtroom would have aided the presentation of the case. Petitioners' counsel declined to even argue (let alone attempt to demonstrate) that such was possible. Asked the same question by the court of appeals, Petitioners' counsel argued that "the one thing that the plaintiffs could have supplied had they been present would have been 'the humanistic aspect of this litigation' not that they would have been able to aid or assist counsel." Appendix to Petition, p. 72. Petitioners do not suggest that the presence of any child could have influenced the jury's fact finding other than by giving it a nonevidentiary basis for its verdict, or that a retrial with the children in attendance would change the outcome other than through the influence of sympathy on the jurors' minds.

While it is settled that children in our society possess civil rights, among them that to due process, it is also settled that, in many respects, these rights may be limited or abridged by reason of age. The right to vote, to hold office and, most im-

portantly, *to sue* is denied to infants. The right to petition the courts for relief is, more accurately, consigned to the parent or guardian of the minor during his minority. In this sense, children may be kept, not only from the courtroom, but from the courthouse by their age. It is fully consistent with fairness that the parent, also entrusted with the child's need for shelter, food, clothing and nurturing, should manage his legal affairs. No one can doubt that the parents of these minor plaintiffs were better able than they to oversee the trial of their claims. No such parent was excluded from the courtroom.

By the electronic means which the district court employed, all Petitioners were able to witness the trial as it occurred and consult with their counsel simultaneously. In a limited trial in which the individual condition of Petitioners was neither a relevant fact nor (in most cases) open to pretrial discovery, the district court respected and preserved Petitioners' practical rights as parties while preventing the risk of a result-oriented verdict. No party was prejudiced by the district court's action.

C. A PLAINTIFF WHO FILES A NON-FRIVOLOUS FEDERAL CLAIM IN FEDERAL COURT MAY NOT, HAVING LOST THE TRIAL WHICH HIS PLEADING DEMANDED, DESTROY SUBJECT MATTER JURISDICTION BY THEREAFTER CONTENDING THAT THE FEDERAL STATUTE ON WHICH HE SUED PROVIDES FOR NO PRIVATE CLAIMS.

All Petitioners who rely upon the Petition's third question of law invoked federal jurisdiction by filing claims against Respondent in federal court, specifically alleging that subject matter jurisdiction was present. As the court of appeals found, *and as these Petitioners do not deny*, "a straight forward reading of plaintiffs' complaint gives the undeniable impression that plaintiffs intended to allege an implied cause of

action under FDCA."[11] The issue of Petitioners' third question is, then, whether a complaint stating an implied cause of action under the Food, Drug and Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq. (1982 ed., Supp. II) was sufficient to vest subject matter jurisdiction in the district court.

In this case, neither the district court nor the court of appeals reached any determination as to whether private claims under the Food, Drug and Cosmetic Act were available. It was simply not necessary to reach that issue before the initial phase of trial. Most plaintiffs had invoked jurisdiction based upon diversity of citizenship which was undisputedly present. The trial would go forward, on schedule, regardless of what additional plaintiffs sought consolidation of their claims, because all plaintiffs were united in their objective to demonstrate to the jury that Bendectin causes birth defects. Neither was the availability of private FDCA claims resolved in either of the precedent decisions upon which the Petitioners exclusively rely, i.e. *Merrell Dow Pharmaceuticals, Inc.* v. *Thompson*, 478 U.S. 804 (1986), or *Thompson* v. *Merrell Dow Pharmaceuticals, Inc.*, 766 F.2d 1005 (6th Cir. 1985).

In the *Thompson* cases, the issue was never reached because, *from the beginning*, no party contended that such private claims were available. *Thompson* concerned citizens of Canada and Scotland who sued Respondent in state court. Other foreign nationals similarly situated had seen the dismissal of their Bendectin lawsuits in federal court on the basis of *forum non conveniens*. Because the *Thompson* plaintiffs desired the advantages of an American forum, they

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[11] In addressing the Petitioners' jurisdictional objection in the court of appeals, Merrell Dow identified 15 Petitioner families in whose cases neither diversity of citizenship nor "federal question" jurisdiction could be demonstrated. Respondent therefore conceded, in the court of appeals, that the district court lacked jurisdiction over the claims of these plaintiffs, who are identified on page 6 of the appendix to the petition. The comment in the body of the petition that the defendant had "concealed [rather than "conceded"] that the district court was without jurisdiction to render judgment" in such cases is clearly a typographical error.

postured themselves to defeat federal jurisdiction on removal. Respondent, as a resident of the forum state, could not remove the actions based on alienage, but only based upon a claim arising under federal law. Though the *Thompson* plaintiffs had alleged violations of the FDCA and damages resulting therefrom, they maintained that these federal allegations were pled solely as elements of state created claims. Since Respondent, as a pharmaceutical manufacturer, was unwilling to contend that the FDCA permitted private claims, it did not there dispute plaintiffs' posture that they had pled only state law claims. Rather, it removed the actions on the premise that the non-federal claims of the plaintiffs "necessarily depended" on the FDCA violations which they alleged.

No party in the *Thompson* cases argued, before *any* court, that the FDCA implied the availability of private claims for violations of the statute. Neither the district court, the court of appeals nor *this Court* had the necessity or opportunity to decide whether such private claims were available. There was simply no controversy on the point.

The rationale for the decision of the court of appeals in *Thompson* was briefly stated:

> The parties agree that the FDCA does not create or imply private right of action for individuals injured as a result of violations of the Act. Federal question jurisdiction would, thus, exist only if plaintiffs' right to relief depended necessarily on a substantial question of federal law. Plaintiffs' causes of action referred to the FDCA merely as one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' causes of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court. [Citations omitted.]

766 F.2d at 1006.

The court of appeals in *Thompson* did *not* reach any conclusion[12] on whether the FDCA creates, by implication, a private right of action for violations. It did not and could not there consider the situation in which a plaintiff, as did Petitioners, expressly invokes federal jurisdiction by pleading claims under the FDCA. Though this Court affirmed the decision of the court of appeals in *Thompson*, it did so pursuant to a very different analysis[13] and, in fact, rejected the reasoning employed by the court of appeals.

> Petitioner also contends that the Court of Appeals' opinion rests on a view that federal question jurisdiction was inappropriate because, whatever the role of the federal issue in the FDCA-related count, the plaintiff could recover on other, strictly state law claims. *See* 766 F.2d at 1006 (noting that "the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA"). To the extent that the opinion can be read to express such a view, we agree that it was erroneous. If the FDCA-related count presented a sufficient federal

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[12] The opinion of this Court in *Merrell Dow* v. *Thompson* echoes the observation of the court of appeals that the parties therein agreed that the FDCA created no private cause of action. However, this Court's opinion suggests that the court of appeals in that case did something more. "In this case, both parties agree with the court of appeals' *conclusion* that there is no federal cause of action for FDCA violations. For purposes of our decision, we *assume* that this is a correct interpretation of the FDCA." 106 S.Ct. at 3234 (emphasis added). However, the Sixth Circuit, in fact, reached no "conclusion" regarding the availability of private FDCA claims. Like this Court, it merely noted the lack of controversy on the point between the parties to that litigation.

[13] This court in *Thompson assumed*, based on the parties self-serving agreement, a congressional decision to preclude private FDCA claims. It held that to sustain "federal question" jurisdiction over a non-federal claim by reason of an essential federal element of that claim, (an alleged FDCA violation) would offend the implied will of Congress, *so assumed*. 106 S.Ct. at 3234. This Court never considered the *actual* will of Congress or the actual availability of private FDCA claims.

> question, its relationship to the other, state law claims would be determined by the ordinary principles of pendent jurisdiction described in *Mine Workers* v. *Gibbs*, 383 U.S. 715 (1966). For the reasons that we have stated, however, there is no federal question jurisdiction even with that possible error corrected.

Merrell Dow Pharmaceuticals, Inc. v. *Thompson*, 478 U.S. 894, 106 S.Ct. 3229, 3237 at footnote 15.

The fact that this Court made an assumption rather than a ruling on the availability of private FDCA claims is reinforced by the dissent:

> It bears emphasizing that the court does not hold that there is no private cause of action under the FDCA. Rather, it expressly states that "for purposes of our decision, we assume that this is a correct interpretation of the FDCA." Ante at 810. The court simply holds Petitioner to its concession that the FDCA provides no private remedy, and decides Petitioner's claim on the basis of this concession. I shall do the same . . .

106 S.Ct. 3229, 3241, footnote 4.

In *Merrell Dow* v. *Thompson*, the parties did concur, based upon their separate circumstances making that position expedient, that the FDCA provides no private claim. With the instant case in its present posture, Petitioners lately assert that no private claim is available, though they improperly cite to this Court's decision in *Thompson* for a *ruling* to that effect that was never made. Respondent as always, agrees that the FDCA provides no private claim. However, unlike the *Thompson* plaintiffs, Petitioners here expressly invoked federal subject matter jurisdiction based upon the premise (which they only *now* renounce) that the FDCA *does* provide a private claim. What prompts Petitioners' current "concession" is the fact that they have tried and lost a lawsuit in a forum which, but for their private FDCA claims, would have no jurisdiction. A plaintiff ought not be permitted to undo a

judgment against him merely by disavowing the sufficiency of his statutory claim which supports jurisdiction.

This is not a case in which this Court can decide whether private FDCA claims *are* available. Because of the trial's outcome, Petitioners are unwilling to here champion their own causes of action. The jurisdictional issue is whether Petitioners' now abandoned reliance on private FDCA claims in originally invoking federal jurisdiction was enough to trigger that jurisdiction. Respondent urges that it was.

In *Mt. Healthy City Board of Education* v. *Doyle*, 429 U.S. 274 (1976), this Court sustained subject matter jurisdiction under 28 U.S.C. § 1331 over a civil claim premised on violations of the First and Fourteenth Amendments and of federal civil rights statutes. This court found no *need* to decide either whether the Fourteenth Amendment provides a private cause of action for violations or whether the plaintiff had stated a sufficient claim under 28 U.S.C. 1983. This court expressly held that such issues *were not jurisdictional questions*:

> The question of whether the Board's argument should prevail, or whether as respondent urged in oral argument, we should, by analogy to our decision in *Bivens* v. *Six Unknown Fed. Narcotics Agents*, 403 U.S. 388 (1971), imply a cause of action directly from the Fourteenth Amendment which would not be subject to the limitations contained in Section 1983, is one which has never been decided by this Court. Counsel for respondent at oral argument suggested that it is an extremely important question and one which should not be decided on this record. We agree with respondent.
>
> The Board has raised this question for the first time in a document filed after its reply brief in this Court. *Were it in truth a contention that the district court lacked jurisdiction, we would be obliged to consider it, even as were are obliged to inquire sua sponte whenever a doubt arises as to the existence of federal jurisdiction. Liberty Mutual Ins. Co.* v. *Wetzel*, 424 U.S. 737, 740 (1976); *Louisville & Nashville R. Co.* v. *Mottley*, 211 U.S. 149,

> 152 (1908). And if there were a § 1983 action, brought under the special jurisdictional provision of U.S.C. § 1343 which requires no amount in controversy, it would be appropriate for this Court to inquire, for jurisdictional purposes, whether a statutory action had in fact been alleged. *City of Keosha* v. *Bruno, supra. However, where an action is brought under § 1331, the catchall federal-question provision requiring in excess of $10,000.00 in controversy, jurisdiction is sufficiently established by allegation of a claim under the Constitution or federal statutes, unless it "clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction . . ."* *Bell* v. *Hood*, 327 U.S. 678, 682 (1946); *Montana-Dakota Utilities Co.* v. *Northwestern Pub. Serv. Co.*, 341 U.S. 246, 249 (1951).
>
> Here, respondent alleged that the Board had violated his rights under the First and Fourteenth Amendments and claimed the jurisdictionally necessary amount of damages. The claim that the Board is a "person" under § 1983, even assuming that correctness of the Board's argument that the § 1331 action is limited by the restrictions of § 1983, is not so patently without merit as to fail the test of *Bell* v. *Hood, supra. Therefore, the questions as to whether the respondents stated a claim for relief under § 1331 is not of the jurisdictional sort which the Court raises on its own motion.* The related question of whether a school district is a person for purposes of § 1983 is likewise not before us. We leave those questions for another day, and assume, without deciding, that the respondent could sue under § 1331 without regard to the limitations imposed by 42 U.S.C. § 1983.

429 U.S. at 278, 279 (emphasis added). The Second Circuit rejected a similar argument by another unsuccessful defendant in *Fogel* v. *Chestnutt*, 668 F.2d 100 (2d Cir. 1981), *cert. denied sub. nom. Currier* v. *Fogel*, 459 U.S. 828 (1981). There, the defendant-appellants argued that a private claim was unavailable under the federal statute upon which plain-

tiff had sued, excusing their failure to previously raise the issue by deeming it "jurisdictional." Rejecting this excuse, the court of appeals distinguished the question whether a federal cause of action states a claim upon which relief can be granted from the question whether such cause of action is insubstantial in a jurisdictional sense.

> This argument is simply one more instance of the fallacy, to which courts as well as counsel have not been immune, of confusing the question of whether a court has jurisdiction with the question of whether a complaint states a claim upon which relief can be granted.
>
> The complaint based jurisdiction on the ICA as well as the Investment Advisors Act of 1940 and the Securities Exchange Act of 1934. It thus stated a claim arising under a law of the United States, of which the district court has jurisdiction under 28 U.S.C. § 1331(a), as well as § 44 of the ICA. *If in fact the statutes relied upon by the plaintiffs did not authorize recovery of damages because of violations of the sort alleged, the complaint failed to state a claim upon which relief could be granted and was subject to dismissal on that ground. However, as defendants would have been the first to assert if they had prevailed in that position and plaintiffs brought another action for the same relief, the dismissal would have been upon the merits and not for lack of jurisdiction.*
>
> Jurisdiction, therefore, is not defeated as respondents seem to contend, by the possibility that the averments might fail to state a cause of action on which petitioners could actually recover. *For it is well settled that the failure to state a proper cause of action calls for judgment on the merits and not for a dismissal for want of jurisdiction.* Whether a complaint states a cause of action on which relief could be granted is a question of law and just as issues of fact must be decided after and not before the court has assumed jurisdiction over the controversy. If the court does later exercise its jurisdiction to

> determine that the allegations in the complaint do not state a ground for relief, then dismissal of the case would be on the merits, not for want of jurisdiction. *Swafford* v. *Templeton*, 185 U.S. 487, 493, 494, 22 S. Ct. 783, 785, 786, 46 L. Ed. 1005; *Binderup* v. *Taft Exchange*, 263 U.S. 291, 305-308, 44 S. Ct. 96, 98-99, 68 L. Ed. 308. The previously carved out exceptions are that a suit may sometimes by dismissed for want of jurisdiction *where the alleged claim under the constitution or federal statutes clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or where such a claim is wholly insubstantial and frivolous.*

668 F.2d at 105, 106 (emphasis added). Had the jury found *against* it, Respondent might now argue the jurisdictional position of the petitioner in *Mt. Healthy* and of the appellant in *Fogel*, though it would meet with no greater success. Likewise, had the plaintiffs in those cases *lost* at trial, the supposed legal insufficiency of their federal statutory claims would have been no more of a jurisdictional shield in their hands than it was when the defendants in those cases invoked it as such. So it is with Petitioners' jurisdictional objection.

This court in *Mt. Healthy* and the Second Circuit in *Fogel* recognized that a federal claim will sustain jurisdiction under 28 U.S.C. § 1331 unless it "clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction . . ." *Bell* v. *Hood*, 327 U.S. 678 (1946). This is true regardless of whether it states a claim upon which relief can be granted.[14] Petitioners' FDCA claims were not frivolous,

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[14] The reason why this two-tiered analysis tends, in practice, to become blurred is that separate decisions on legal sufficiency as opposed to jurisdictional sufficiency are, in many cases, practically indistinguishable to the parties. An appropriate example is the decision of the district court in *Griffin* v. *O'Neal, Jones & Feldman, Inc.*, 604 F. Supp. 717 (S.D. Ohio 1985). In *Griffin*, decided by the district court shortly *after* the jury verdict in the instant case, plaintiffs brought claims nearly identical to those in the instant case though they concerned a different drug. Such included claims for negligence, breach of warranty, strict liability, FDCA violations, "fraud"

though Respondent still maintains that they were legally insufficient. As late as this Court's decision in *Thompson* (well after the trial below) the availability of private FDCA claims was an open question and continues to be such. Accordingly, Petitioners' claims conferred subject matter jurisdiction on the district court.

The legal insufficiency of the Petitioners' FDCA claims, like many other substantive defenses advanced by the Respondent but never ruled upon, were deferred by the district court to permit trial of the common question whether Bendectin causes human birth defects. This issue was an essential one to all the claims of all the Petitioners and no less to their claims under the FDCA. There was no *adjudication* of the claims under the FDCA prior to the jury verdict, since the court, in an effort to expedite the progress of a mass tort litigation by trial of its single universal issue, found no need to reach this *non jurisdictional* question before trial.

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and a separate claim for punitive damages. The district court dismissed the federal claims *on their merits* under Rule 12(b)(6), Fed. R. Civ. P., 604 F. Supp. at 718. The non-federal claims were then dismissed without prejudice under *United Mine Workers* v. *Gibbs*, 383 U.S. 715, 86 S. Ct. 2130, 16 L. Ed. 2d 218 (1966), since they had been "orphaned" by *pre-trial* dismissal of the federal claims on which jurisdiction depended. There can be no doubt, however, that the federal claims, themselves, were *adjudicated on their merits*. Had the plaintiffs in *Griffin* refiled their FDCA and RICO claims in state court, the defendants would have the complete defense of *res judicata* by reason of the district court's decision. *Cannon* v. *Loyola University of Chicago*, 609 F. Supp. 1010, 1015 (N.D. Ill. 1985), *aff'd*, 784 F.2d 777 (7th Cir. 1986). It happens that the Plaintiffs in *Griffin* were represented by counsel for Petitioners, Mr. Chesley.

IV. CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

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No. 88-704

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1988

IN RE: BENDECTIN LITIGATION

SARAH ANN HOFFMAN, *ET AL.*
ELIZABETH ANN DAVIS, *ET AL.*
and SHANE ROSS WOOD, ETC. *ET AL.*,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the United States Court Of Appeals for the Sixth Circuit

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INTRODUCTION

To illustrate the difference between the truth and what human beings perceive, Plato told the parable of the cave. In it, certain persons were consigned to live in a cave far from its opening with their legs and necks chained so that they could not move their heads and could not look in any direction but straight ahead at a wall. Behind and above them at a distance blazed a great fire, and between the fire and the prisoners was an elevated passageway on which there was much activity. But the people in chains could never see this activity directly; all they knew of it was what they could discern from the shadows of moving figures projected on the wall in front of them. "To them," reasoned Plato, "the truth would be literally nothing but the shadows of the images." *The Republic*, Chap. 7.

In our judicial system today, there is manifest danger that, as civil juries are increasingly shielded from certain sights, events, and facts that are naturally meaningful and evocative in the ordinary course of things, juries will be no more able to discern the truth in a trial than were the prisoners in Plato's cave. What is at stake is a jury system built on the assumption that truth flows from knowledge, and justice from truth. If juries are consigned to find truth not in that knowledge which is naturally most enlightening but instead among the shadows of images on a wall, what results is not justice at all, but rather, in Plato's words, "the images or shadows of images of justice." *Ibid.*

Two orders transformed the trial in this case into an abstract fact-finding exercise, sanitizing it way be-

yond all reasonable justification and, indeed, way beyond the dictates of fairness. These orders plainly fit into this trend of unduly keeping juries in the dark. Occurring in the same case, the orders present the Court with a rare opportunity to reaffirm the critical importance of the enlightened jury writ large and to resolve disputes among courts on whether juries can constitutionally be kept unenlightened when it comes to understanding specifically how the plaintiff claims to have been injured by the defendant's alleged conduct.[1]

By the trifurcaction order, the jury was forced to decide whether defendant's drug caused birth defects, without the benefit of any plaintiff-specific evidence on causation. The order vividly shows that the simple act of a carving up an issue like causation and trying it initially as a purely abstract question indeed substantially changes the rules of proving causation. By excluding certain plaintiff-specific evidence on causation even though it is admissible, and leaving only expert testimony devoid of references to what effect the drug had on these plaintiffs, the order deprived the jury of that chance to assess plaintiffs' theory of causation in its entirety.

By the plaintiff exclusion order the jury was shielded from visibly deformed plaintiffs. This protected defendants from the prospect that a juror, by

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[1] Conflicting decisions include the following: *Compare, Helminski v. Ayerst Laboratory, etc.*, 766 F.2d 208 (6th Cir. 1985); *Carlisle v. County of Nassau*, 64 App. Div. 2d 15, 408 N.Y.S. 2d 114 (1978); *Florida Greyhound Times, Inc. v. Jones*, 60 So.2d 396 (Fla. 1952); *with, Dickson v. Boler*, 269 Minn. 334, 130 N.W.2d 526 (1964); *Morley v. Superior Court*, 131 Ariz. 85, 638 P 2d 1331 (1981).

the mere sight of a deformed plaintiff, would broadly assume defendant's drug was the cause. But, ironically and quite significantly, the order did nothing to protect plaintiffs from the equally threatening prospect that a juror, seeing no deformed victims in the courtroom when seeing some would have been natural, would broadly assume defendant's drug does not cause deformities.

These orders operated in unison to ensure that the jury had only the most disengaged and refracted view of the matter before them.

I. THE COURT SHOULD GRANT CERTIORARI AND HOLD THAT TRIFUCATION ORDERS THAT PARSE UP THE CAUSATION ISSUE UNFAIRLY DEPRIVE A PLAINTIFF OF A FAIR TRAIL BY ELIMINATING HIS OPPORTUNITY TO SHOW WITH WHATEVER ADMISSIBLE EVIDENCE HE HAS THAT HIS THEORY OF CAUSATION IS PLAUSIBLE.

Under the guise of case management, trifucation transformed trial in this case into an abstract exercise premised on the assumption that causation could only be discussed and decided in a sterile atmosphere far removed from any specific consideration of how these plaintiffs were affected by defendants' drug. The Court should intervene to consider whether such orders have a place in a fair trial, whether such orders ever fairly narrow the jury's range of inquiry, and when such orders force the jury to find answers based on unnecessarily abstract and refracted evidence.

This Court has long recognized that an essential component of a fair trial is "a jury capable and willing to decide the case solely on the evidence before it." *McDonough Power Equipment, Inc. v. Greenwood*, 464 U.S. 548, 104 S. Ct. 845, 849, 78 L.Ed. 2d 663 (1984).

Clearly, then, by extension of the Court's own definition, if a fair trial depends on whether the jury can resolve a matter based only on the evidence before it, there can be no fair trial unless the jury has before it *all* the evidence it needs to decide the matter.

Trifurcation operates to deprive the jury of the necessary context for judging causation. Discussing the defendant's conduct without reference to the harm which the plaintiff sustained deprives causation of its proper context. It is the context of the causation issue, the ability to project abstract information such as scientific data on a background of actual events and circumstances, which unlocks the door to complicated questions of causation. A causation issue that is never permitted to emerge from the realm of the abstract is destined to remain arcane and, thus, is all the more subject to guesswork resolution by a jury. Placing the issue of causation in context by means of plaintiff-specific information does not add to the complication of it; rather such information serves as an indispensable solvent, breaking down the issue into a form that a jury can best understand and, therefore, most easily and accurately resolve. In a fundamental sense, a plaintiff who has been denied the opportunity to show how he was harmed by the defendant's conduct has been deprived of an essential means for demonstrating the plausibility of his theory of causation. That opportunity was missing from this case and, to that extent, plaintiffs were denied a fair trial. Petitioners respectfully urge review of this issue on certiorari and reversal.

II. THE COURT SHOULD RECOGNIZE THE PRESUMPTIVE RIGHT OF A PLAINTIFF TO BE PRESENT AT HIS OWN TRIAL, AS A DERIVATIVE OF HIS RIGHT TO A FAIR TRIAL.

Defendant underscores precisely why the plaintiff exclusion issue is so ripe for resolution by this Court. Defendant sloughs off any presumptive right of plaintiffs to be present at their entire trial—even though *Helminski* appeared to recognize that right, at least until this case came along—and seems to suggest that any right plaintiffs might have had to be present at their own trial began and ended with serving "as witnesses or as human demonstrative evidence." Opposition to Petition, p. 19. These aspects of the plaintiff exclusion issue warrant this Court's attention in this precise context because, if a visibly deformed plaintiff is excludable based solely on his physical appearance, the Federal system will have adopted an unjustified presumption of excludability that operates to the plaintiff's unfair disadvantage and to the defendant's palpable advantage.

To suggest that there is no valid purpose for the physical presence at trial of a plaintiff who will not be called as a witness is to discount the importance of the visual aspect of a trial to the jury's fact-finding function. The jury's fact-finding function is at once associative and sensate, meaning that in a trial setting jurors apprehend the truth in part by associating what they hear with what they see. If jurors could hear witnesses but not see them, it would no doubt have a significant impact on their decisions. In weighing the evidence, jurors inevitably consider what each witness had to say and whatever else they were able to observe about the witness. So, too, the arguments of counsel and the instructions from the court have

visual as well as auditory impact because the attorneys and the judge, along with the witnesses, the parties, and the onlookers, constitute the trial setting, in both an audible and visual sense. While courts cautiously control the audible contributions from the various players at a trial (e.g., by prohibiting remarks from onlookers) there is less reason for eliminating any players from the vision of the jury altogether. Artificial manipulation of the trial's visual atmosphere carries the constant risk of unwittingly benefiting one side over the other, by removing from the jury's view someone who would naturally be present, without the appropriate explanations to the jury.

The plaintiff is no less crucial to the jury's visualization of the dispute than are the other players mentioned above. His presence at trial signifies that he is carrying the case to the defense. Yet defendant mocks the notion that a plaintiff's physical presence at trial serves any purpose beyond his testimony. We emphatically disagree. Defendant recoils at the thought that jurors will pay attention to a deformed plaintiff during trial, and that he or she will serve as a constant visual reminder to the jury of the harm defendant is alleged to have caused. Defendant is merely hiding from reality, for in a lawsuit the plaintiff personifies the dispute, giving it a human face. It is foolhardy to imagine that the system does not already contemplate that a jury will derive meaning from a plaintiff's physical appearance. Surely, defendant would not propose that we also exclude the victim of alleged sex discrimination whose physical appearance constantly reminds the jury that she is a woman; or the victim of alleged racial discrimination whose physical appearance constantly reminds the jury

that he is black; or the elderly victims of fraud whose physical appearance constantly reminds the jury that they are aged and vulnerable. Moreover, it is totally illogical to suggest there is something inherently unfair about a plaintiff being able to *advance* his cause by appearing in court. At the risk of stating the obvious, *that* is the reason why every plaintiff comes to court in the first place. So the prospect of excluding a plaintiff whose personal appearance could advance his cause—for example, by evoking sympathy—unfairly deprives that plaintiff of his right to present himself to the jury as the aggrieved party and unduly restricts the jury's ability to visualize the case as a human dispute.

On the other side, an order excluding the plaintiff can provide the defendant with a windfall, as it indeed did in this case. In a case such as this predicated on charges that defendant's drug caused plaintiffs' birth defects, the total absence from the courtroom of any plaintiffs with visible deformities serves as potent negative evidence in defendants' favor. It gives the jury reason to wonder why, if the drug has caused so many defects, every person who has presented himself at the trial appears to be perfectly normal. This false impression undercut plaintiffs' claim in this case, particularly since the district court did not stop with excluding visibly deformed plaintiffs. It also barred any evidence detailing plaintiffs' defects from being introduced to the jury in this phase. To extend the analogy of the sex-discrimination suit, this would be comparable to barring the female plaintiff from the courtroom *and* precluding all references that would give away her gender. The doubt thus created, like the unnecessary doubt fostered by the district

court through the trifurcation and plaintiff exclusion orders, is insidious and has no place in a fair trial.

The question whether or not a plaintiff exclusion order has a place in a fair trial also necessarily involves due process considerations. Yet the minimal safeguard of a hearing was lacking here, as was any hint of the criteria which persuaded the district court to exclude plaintiffs, beyond the obvious fact that they were visibly deformed. Not only is there a compelling need for this Court's enlightenment on the nature of the right of a plaintiff to be present at his entire trial, but if that be a presumptive right, the lower courts should have the benefit of the Court's guidance as to the precise criteria to weigh in resolving conflicts between a visibly deformed plaintiff's right to a fair trial and the defendant's right to a fair trial.

III. FEDERAL QUESTION JURISDICTION DOES NOT EXIST MERELY BECAUSE PETITIONERS ALLEGED IN THEIR COMPLAINTS A VIOLATION OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT

Respondent devotes the major portion of its argument supporting its proposition that alleging a violation of the Federal Food, Drug and Cosmetic Act (52 Stat. 1040, as amended, 21 U.S.C. Sec. 301 et seq., 1982 ed. Supp. II) within a cause of action for negligence instills within the trial court federal question jurisdiction. While respondent recognizes the fact that a right to private action under the Federal Food, Drug and Cosmetic Act does not exist, respondent argues that merely pleading a violation of the Act creates federal question jurisdiction. In so arguing, the respondent adopts the position most recently taken by the Court of Appeals for the Sixth Circuit in the instant case, which position contradicts the

Court of Appeals' earlier stance in the instant case as set forth in *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 766 F.2d 1005 (6th Cir. 1985), as well as this Court's holding in *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986).

It is the contradictory nature of the foregoing holdings which makes this issue one which is appropriate for the granting of certiorari. On one hand, the Court of Appeals for the Sixth Circuit has held, as has this Court, that pleading an alleged violation of the Federal Food, Drug and Cosmetic Act in a complaint filed in a state court, does not create federal question jurisdiction for purposes of removal. On the other hand, the Court of Appeals has held that pleading the same identical allegation in a complaint filed in federal court does create federal question jurisdiction.[2] These varying decisions cannot be reconciled.

In support of respondent's argument, respondent relies particularly upon two cases: *Mt. Healthy City School District Board of Education v. Doyle*, 429 U.S. 273 (1976) and *Fogel v. Chestnutt*, 668 F.2d 100 (2nd Cir. 1981) cert. denied sub. nom. *Currier v. Fogel*, 459 U.S. 828 (1981). However, respondent's reliance is misplaced. These cases do not address the issue before this Court.

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[2] The Court of Appeals dismissed without prejudice, thirteen actions brought by Ohio citizens in federal court, in which the respondent had conceded that no federal question jurisdiction was invoked. As to all other suits brought by Ohio citizens in federal court, in which the complaints filed were identical to those filed in the cases dismissed without prejudice and as to which respondent had not conceded an absence of federal question jurisdiction, the Court of Appeals held that the district court did have federal question jurisdiction.

In *Mt. Healthy City School District Board of Education v. Doyle*, supra, respondent had alleged causes of action under the First and Fourteenth Amendments to the Constitution, and asserted jurisdiction pursuant to 28 U.S.C. Sections 1343 and 1331. The Court assumed jurisdiction under 28 U.S.C. Section 1331. After certiorari had been granted, the petitioner raised the issue of whether respondent's only substantive constitutional claim arose under 42 U.S.C. Section 1983, and if so, whether petitioner was exempt from liability. Irrespective of the petitioner's issue regarding 42 U.S.C. Section 1983, jurisdiction was sufficiently established by the allegation of a claim (violation of respondent's right to free speech) under the Constitution. Further, even if 42 U.S.C. Section 1983 was a substantive basis for a claim by respondent, Section 1983 unquestionably provided respondent with a private right of action.

In *Fogel v. Chestnutt*, supra, a stockholder's derivative complaint was filed alleging a cause of action for breach of fiduciary duty to make full disclosure, wherein jurisdiction was alleged pursuant to the Investment Company Act of 1940, the Investment Advisors Act of 1940, and the Securities Exchange Act of 1934. The Court of Appeals for the Second Circuit had previously held, and the defendants had previously agreed, that the plaintiffs could in fact recover damages pursuant to the Investment Company Act of 1940. Other courts had also previously held that an implied right of private action existed under the Investment Advisers Act and the Investment Company Act. Upon the second appeal in the case, the defendants presented the argument that no private right of action for damages existed under the statute.

The Court of Appeals did not again determine the question, but instead, relied upon the principle of the law of the case, finding the argument presented by defendants was one which went to the merits as opposed to jurisdiction. In so holding, the Court of Appeals did discuss various cases which spoke to the issue of federal jurisdiction, but none of these cases clearly resolves the question which is presented by the instant case to this Court.

Thus, the two cases upon which Respondent relies provide no answer to the contradictory holdings of the Court of Appeals for the Sixth Circuit in the instant case. Both of the cited cases involved situations wherein a private right of action had already been recognized. Here, no private right of action exists, nor has one been previously recognized.

Respondent also argues that because a verdict has been rendered against the petitioners, federal question jurisdiction should be found to exist. However, the stage of the proceedings should have no bearing whatsoever upon a jurisdictional issue. Any action by a court without jurisdiction is a nullity and a party can attack jurisdiction at any time, even after judgment has been rendered. *Amer. Fire & Cas. Co. v. Finn*, 341 U.S. 6 (1951).

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